



# ALABAMA MEDICAID AGENCY REQUEST FOR PROPOSALS

<b>RFP Number: 2021-Pharmacy-01</b>	<b>RFP Title: Alabama Medicaid Agency Pharmacy Clinical Support</b>	
<b>RFP Due Date and Time:</b> January 13, 2022 by 5:00pm Central Time		<b>Number of Pages: 91</b>
<b>PROCUREMENT INFORMATION</b>		
<b>Project Director: Amanda Singletary</b>		<b>Issue Date: October 15, 2021</b>
<b>E-mail Address:</b> PharmacyRFP@medicaid.alabama.gov <b>Website:</b> <a href="http://www.medicaid.alabama.gov">http://www.medicaid.alabama.gov</a>		<b>Issuing Division:</b> Clinical Services and Support / Pharmacy
<b>INSTRUCTIONS TO VENDORS</b>		
<b>Return Proposal to:</b> <b>Alabama Medicaid Agency</b> <b>Attn: Amanda Singletary</b> <b>Lurleen B. Wallace Building</b> <b>501 Dexter Avenue</b> <b>PO Box 5624</b> <b>Montgomery, AL 36103-5624</b>		<b>Mark Face of Envelope/Package:</b> Alabama Medicaid Agency Pharmacy Clinical Support RFP <b>RFP Number:</b> 2021-Pharmacy-01 <b>RFP Due Date:</b> January 13, 2022 by 5:00 pm CT <b>Firm and Fixed Price:</b>
<b>VENDOR INFORMATION</b> <i>(Vendor must complete the following and return with RFP response)</i>		
<b>Vendor Name/Address:</b>	<b>Authorized Vendor Signatory:</b> (Please print name and sign in ink)	
<b>Vendor Phone Number:</b>	<b>Vendor FAX Number:</b>	
<b>Vendor Federal I.D. Number:</b>	<b>Vendor E-mail Address:</b>	

## Section A. RFP Checklist

1. \_\_\_\_\_ **Read the *entire* document.** Note critical items such as: mandatory requirements; supplies/services required; submittal dates; number of copies required for submittal; licensing requirements; contract requirements (i.e., contract performance security, insurance requirements, performance and/or reporting requirements, etc.).
2. \_\_\_\_\_ **Note the project director's name, address, phone numbers and e-mail address.** This is the only person you are allowed to communicate with regarding the RFP and is an excellent source of information for any questions you may have.
3. \_\_\_\_\_ **Take advantage of the "question and answer" period.** Submit your questions to the project director by the due date(s) listed in the Schedule of Events and view the answers as posted on the WEB. All addenda issued for an RFP are posted on the State's website and will include all questions asked and answered concerning the RFP.
4. \_\_\_\_\_ **Use the forms provided,** i.e., cover page, disclosure statement, etc.
5. \_\_\_\_\_ **Check the State's website for RFP addenda.** It is the Vendor's responsibility to check the State's website at [www.medicaid.alabama.gov](http://www.medicaid.alabama.gov) for any addenda issued for this RFP, no further notification will be provided. Vendors must submit a signed cover sheet for each addendum issued along with your RFP response.
6. \_\_\_\_\_ **Review and read the RFP document again** to make sure that you have addressed all requirements. Your original response and the requested copies must be identical and be complete. The copies are provided to the evaluation committee members and will be used to score your response.
7. \_\_\_\_\_ **Submit your response on time.** Note all the dates and times listed in the Schedule of Events and within the document, and be sure to submit all required items on time. Late proposal responses are *never* accepted.
8. \_\_\_\_\_ **Prepare to sign and return the Contract, Contract Review Report, Business Associate Agreement and other documents** to expedite the contract approval process. The selected vendor's contract will have to be reviewed by the State's Contract Review Committee which has strict deadlines for document submission. Failure to submit the signed contract can delay the project start date but will not affect the deliverable date.

<b>This checklist is provided for assistance only and should not be submitted with Vendor's Response.</b>
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## Section B. Schedule of Events

The following RFP Schedule of Events represents the State's best estimate of the schedule that shall be followed. Except for the deadlines associated with the vendor question and answer periods and the proposal due date, the other dates provided in the schedule are estimates and will be impacted by the number of proposals received. The State reserves the right, at its sole discretion, to adjust this schedule as it deems necessary. Notification of any adjustment to the Schedule of Events shall be posted on the RFP website at [www.medicaid.alabama.gov](http://www.medicaid.alabama.gov).

EVENT	DATE
RFP Issued	10/15/2021
Answers to Questions Posted As Available	11/03/2021 – 12/08/2021
Final Posting of Questions and Answers	12/08/2021
Proposals Due by 5 pm CT	01/13/2022
Evaluation Period	01/14/2022-02/11/2022
Contract Award Notification	03/09/2022
**Contract Review Committee	06/02/2022
Official Contract Award/Begin Work	07/01/2022 **

\* \*By State law, this contract must be reviewed by the Legislative Contract Review Oversight Committee. The Committee meets monthly and can, at its discretion, hold a contract for up to forty-five (45) days. The “Vendor Begins Work” date above may be impacted by the timing of the contract submission to the Committee for review and/or by action of the Committee itself.

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# **I. Background**

The Alabama Medicaid Agency is requesting proposals from vendors with expertise for a plan to perform clinical support services for the Pharmacy Program. Services required are outlined through this Request for Proposal (RFP). The Vendor shall provide clinical and specified administrative support for the Preferred Drug Program and the Hemophilia Management Standards of Care Audit Program. The Vendor will be required by the State to operate under all provisions of the Omnibus Budget Reconciliation Act (OBRA) 1990, the Social Security Act, and all applicable state and federal laws. State regulatory authority is derived from Alabama Act No. 2003-297 and Alabama Medicaid Agency Administrative Code Chapter 16. The projected implementation date of the RFP is July 1, 2022.

Currently, Alabama Medicaid uses First Data Bank (FDB) for the management of the drug file to include pricing. Gainwell Technology is the current fiscal agent responsible for the MMIS system and claims processing. More pharmacy specific information can be found on the Alabama Medicaid website [www.medicaid.alabama.gov](http://www.medicaid.alabama.gov).

The selected Vendor to whom the contract is awarded shall be responsible for the performance of all duties contained within this RFP for the firm and fixed price quoted in the Vendor's proposal to this RFP. All proposals must state a firm and fixed price for the services described.

All information and amendments contained in this RFP reflect the best and most accurate information available to Medicaid at the time of the RFP preparation. No inaccuracies in such data shall constitute a basis for change of the payments to the Vendor or a basis for legal recovery of damages, actual, consequential, or punitive.

## **A. Preferred Drug Program**

Since the formulary expansion of OBRA 1990, Medicaid expenditures in Alabama for outpatient drugs have escalated from approximately \$60 million in 1990 to a total cost of \$750 million in Fiscal Year 2019. This dramatic change is directly related to the broad coverage mandated by OBRA 90, the increase in recipient enrollment, and the increase in the costs of covered medications. Medicaid has aggressively sought to address pharmacy issues through the implementation of various programs with a clinical focus. In addition to the implementation of cost saving programs such as coverage for over-the-counter medications, a prescription brand limit, and a state Average Acquisition Cost (AAC) program, Medicaid has focused on programs that foster safe, appropriate, and effective drug therapy. These programs include retrospective Drug Utilization Review (DUR), prospective DUR, provider education/academic detailing, prior authorization, and the mandatory Preferred Drug Program and listings (PDL).

In accordance with Alabama Act No. 2003-297, Alabama Medicaid implemented a mandatory Preferred Drug Program (PDP) effective November 2003. The PDP operates with three basic goals. The primary goal of the program is to foster safe, appropriate, and effective drug therapy. Clinical considerations and patient care take precedence over all other deliberations and decisions. The program provides Medicaid with a fundamental and foundational drug management system through a quality of care driven approach.

Secondly, the PDP is designed to serve as an educational system for both prescribing physicians and dispensing pharmacists. The PDP does not usurp the prescribing prerogatives of physicians. A physician has and maintains the ability to prescribe any necessary medication. Use of a designated preferred drug is encouraged when medically appropriate.

Additionally, the PDP offers a mechanism to control the increasing costs associated with medical care. Properly employed drug therapy in managing disease contributes substantially to improved health outcomes and lower overall health care costs. Also, the PDP encourages appropriate generic and over-the-counter (OTC) drug utilization.

Legislation mandates that Medicaid is to develop the PDL in coordination with the Pharmacy and Therapeutics (P&T) Committee. The P&T Committee is comprised of a minimum of five physicians and three pharmacists that are licensed to practice in the State of Alabama. This Committee has met four times the last Fiscal Year, which will be the minimum amount of meetings expected going forward, with additional meetings to be held as necessary. All meetings are, and will be conducted in Montgomery, AL, at a designated location, usually at the Medicaid building. Medicaid makes arrangements for all meeting rooms. The P&T Committee functions include advising Medicaid on prior authorization, PDL reviews and coverage determinations. For purposes of the PDP, the Committee performs in-depth clinical reviews of targeted classes of drugs and makes recommendations to Medicaid utilizing reviews provided by the Vendor. These recommendations are submitted by written ballot, announced during the P&T meeting and reflected in the meeting minutes.

A product of the coordination of the PDP and P&T Committee is the Preferred Drug List (PDL). The PDL is composed of preferred brands, most generics, and covered over-the-counter (OTC) products of targeted and reviewed classes of drugs and do not require prior authorization. Non-preferred agents for the classes reviewed remain covered but require prior authorization.

More information related to Medicaid PDL and the P&T Committee may be found on the Medicaid website [www.medicaid.alabama.gov](http://www.medicaid.alabama.gov) under Programs/Pharmacy/Preferred Drug List and Programs/Pharmacy/Pharmacy and Therapeutics Committee. The selected Vendor will be expected to draft, maintain, and present clinical packets at the level or higher of current meeting packets. The selected Vendor should be very familiar with the current policies, clinical packet design, and all aspects of the current PDL/P&T program upon contract award. Medicaid is open to recommendations from the Vendor as to drug classes or sub-classes appropriate for future PDL reviews.

Vendor will be responsible for:

- Preparing and conducting pharmacotherapy clinical reviews
- Maintaining Preferred Drug Program's related listings
- Providing drug coverage recommendations
- Providing clinical pharmacist or clinical staff knowledgeable in the respective drug class area to attend and present the clinical packet information and administrate the P&T Meetings to be held in Montgomery, Alabama.

## **B. Hemophilia Audit Program**

Hemophilia is an inherited disease that prevents the blood from clotting properly. People with hemophilia have a deficiency in their blood protein, also known as the "clotting factor," that is necessary to clot the blood and stop the bleeding. One way to manage the disease is to administer blood factor replacement drugs to the patient. These factor replacement drugs are extremely costly and are usually dispensed through specialty pharmacies. For calendar year 2020, Medicaid spent \$23,853,529.49 on clotting factor replacement drugs for 111 Medicaid-



eligible patients through the outpatient pharmacy program. Medicaid currently has approximately 16 active providers of blood clotting factors through the outpatient pharmacy program.

In January 2008, Medicaid implemented a Hemophilia Standard of Care (SOC) to ensure all recipients receive a minimum standard of care and to remove inconsistencies in how the clotting factor is provided. The SOC requires that health care professionals providing hemophilia-related services must meet minimum hemophilia-related continuing education requirements each year and follow a minimum standard on patient care and coordination. The SOC also ensures clinically appropriate services are being provided to hemophilia patients, and Medicaid (or its designated representative) shall monitor providers of blood clotting factors by prospective and retrospective audits, as well as a patient/family/caregiver satisfaction survey. The SOC can be found on Medicaid's website in its Administrative Code Rule No. 560-X-16-.31 Hemophilia Management Standards of Care, or in Attachment H. All auditing components must receive approval from Medicaid prior to their distribution.

The selected Vendor should be very familiar with the current hemophilia policies, Standard of Care, and all aspects of the current hemophilia program upon contract award. More information can be found on the Medicaid website [www.medicaid.alabama.gov](http://www.medicaid.alabama.gov) under Programs/Pharmacy/Hemophilia Management.

Vendor will be responsible for:

- Audit criteria and procedures development
- Conducting audits
- Notifying provider of audits and results
- Coordination with Medicaid regarding results from the audit
- Providing a Hemophilia Audit Coordinator to conduct and oversee audit activities

## II. Scope of Work

Vendor's proposal must present a plan to provide clinical and specified administrative support for the Preferred Drug Program and the Hemophilia Management Standards of Care Audit Program.

The Vendor must:

1. Support the continued development and operation of the Medicaid Preferred Drug Program (PDP) (Section II.A) by providing:
  - a. Current clinical research for review by the P&T Committee
  - b. Qualified staff to present information to the P&T Committee
  - c. Written materials relevant to PDP's operation
  - d. PDP document/listings updates
  - e. Cost savings recommendations and reports
2. Support the continued development and operation of the Hemophilia Audit Program (Section II.B) by providing:
  - a. Annual provider and recipient audits
  - b. Hemophilia Audit Manual Updates
3. Support the continued development and operation of Medicaid's Pharmacy Clinical Support Unit by having access to relevant reference tools (Section II.C)

Note: Vendor will present material previously prepared by the previous vendor for the P&T Committee Meetings scheduled after contract award.

The Vendor must perform all of the services listed below and as further explained in the Attachments to this RFP.

### **A. Preferred Drug Program**

The Vendor must provide clinical research, data and reviews to the P&T Committee and/or Medicaid regarding preferred drug reviews and drugs to be considered for prior authorization, overrides, or coverage issues as requested by Medicaid or the P&T Committee. All reviews are to follow Medicaid policy.

*Vendor, in a timely and professional manner, must provide all contract deliverables utilizing formats and time lines approved by Medicaid.*

The following listing includes, but is not limited to, the responsibilities related to the preferred drug program component of this contract.

As a part of the proposal, the Vendor must provide a detailed description for each of the contract deliverables listed below:

Contract Deliverables		Tasks	Deliverable Frequency
1	<b>Pharmacological Clinical Review Packet</b>	Provide clinical information via clinical reviews of targeted classes or sub-classes of drugs to the Medicaid Pharmacy and Therapeutics (P&T) Committee.	Four per year (minimum)
		<u>Review Format</u>  Reviews are to be developed in a consistent format as agreed upon with Medicaid. Each class review includes the following sections: <ul style="list-style-type: none"> <li>• Overview</li> <li>• Evidence-Based Medicine and Current Treatment Guidelines</li> <li>• Indications</li> <li>• Pharmacokinetics</li> <li>• Drug Interactions</li> <li>• Adverse Drug Events</li> <li>• Dosing and Administration</li> <li>• Effectiveness</li> <li>• Cost</li> <li>• Conclusions</li> <li>• Recommendation</li> <li>• References</li> </ul>	

		<p><u>Clinical Information Specifics:</u></p> <p>Reviews must be developed and presented according to the AHFS classification system unless specified by Medicaid.</p> <p>Medicaid must approve the groups and subgroups by AHFS classification in which the Contractor intends to conduct and present the reviews. Contractor is to obtain Medicaid approval prior to deviating from the approved groupings and/or sub-groupings.</p> <p>Clinical information must also provide recommendations for inclusion/exclusion of reviewed drugs in the Medicaid's Preferred Drug Program and PDL listings.</p>	
		<p><u>Supporting Documentation</u></p> <p>Supporting documentation must be available upon request by the P&amp;T Committee or Medicaid.</p>	
		<p><u>References</u></p> <p>References are to be included in the review packets. All pertinent studies and clinical literature must be reviewed by the Contractor and referenced in the reviews.</p>	
2	<p><b>Pharmacological Clinical Review Packet</b></p> <ul style="list-style-type: none"> <li>New Drug Review Section</li> </ul>	<p>Provide clinical information via clinical reviews to the Medicaid P&amp;T Committee of drugs new to the market as well as drugs that the P&amp;T Committee believes should be re-evaluated.</p> <p>Clinical information must also provide recommendations for inclusion/exclusion of reviewed drugs in the Medicaid's Preferred Drug Program and PDL listings.</p> <p>Review information provided to the P&amp;T Committee must be based on all peer reviewed literature and studies, evidence based medicine, and national guidelines.</p>	<p>As requested in conjunction with P&amp;T Review</p> <p>New Drug Reviews are scheduled once requested by manufacturer's representative and based on meeting availability</p>

3	<b>Inclusion/Exclusion Drug Listing</b>	<p>Recommend inclusion/exclusion of drugs to be considered in clinical reviews for P&amp;T meetings based on AHFS or other classification, including but not limited to FDB coding.</p> <p><u>P&amp;T Review Drug Listing</u></p> <p>Provide a list of drugs (in a format approved by Medicaid) from Medicaid's drug file that fall into prior approved AHFS classifications, and add/delete drugs that fall into/out of the particular AHFS classification(s) along with documentation to clinically support why those particular drugs need to be included/excluded from the review.</p> <p>Medicaid will approve the first draft of the drug list and return to Contractor as defined in a timeline approved by Medicaid for each respective review.</p> <p>The Contractor must provide Medicaid with a "clean," approved, final drug list as defined in a timeline approved by Medicaid for each respective review.</p> <p><u>Brand vs. Generic Recommendation</u></p> <p>Make recommendations to Medicaid regarding drugs' brand versus generic, and OTC versus legend status.</p>	Quarterly (minimum)
4	<b>P&amp;T Meeting Materials</b>	<p><u>Draft Meeting Materials</u></p> <p>Draft materials must be sent to Medicaid via electronic format (historically email) and must be approved by Medicaid.</p> <p>A timeline for all drafts should be approved by Medicaid for each P&amp;T review and must be followed by the Contractor.</p> <p>Draft materials include, but are not limited to:</p> <ul style="list-style-type: none"> <li>• Meeting agenda</li> <li>• Informational packets</li> <li>• Ballots</li> </ul>	Quarterly (minimum)

		<ul style="list-style-type: none"> <li>• Meeting timeline (internal and external)</li> <li>• Manufacturer meeting notification</li> <li>• Member meeting notification</li> <li>• PDL final document</li> <li>• Clinical packet</li> </ul>	
		<p><u>Approved Meeting Materials</u></p> <p>Provide approved materials (informational packets, meeting agenda, etc.) to all P&amp;T members, applicable manufacturer representatives and necessary Medicaid staff in accordance with Medicaid approved timeline.</p> <p>P&amp;T Members:</p> <p>The meeting's materials must be sent by Contractor to the P&amp;T members electronically at least (2) two weeks prior to the meeting.</p> <p>The electronic clinical binders and the approved manufacturers' written comments are emailed, and jump drives (provided by the Contractor) are mailed overnight. There are currently eight voting members of the P&amp;T Committee.</p> <p>AL Medicaid Staff:</p> <p>Meeting materials must also be supplied to Medicaid in electronic format for posting to the Medicaid web site. Versions should be sent to Medicaid on jump drives (provided by Contractor) and via email.</p> <p>Copies for Medicaid staff may be directed to the PDL Administrator, Pharmacy Services.</p>	Four times year (minimum)

<b>5</b>	<b>Committee Member Meeting Notification</b>	Provide written meeting notification, electronically, to P&T members prior to mailing the review packet as defined in a timeline approved by Medicaid for each respective review.	Quarterly (minimum)
<b>6</b>	<b>Manufacturer P&amp;T Meeting Notification</b>	Notify manufacturers of upcoming P&T reviews <u>and</u> maintain database of manufacturer contact information sheets as defined in a timeline approved by Medicaid for each respective review.  Notifications are sent with receipt confirmation method applicable to delivery method.	Quarterly (minimum)
<b>7</b>	<b>Public P&amp;T Meeting Notification</b>	Provide an electronic version of public notice of meeting and drug classes scheduled for review to Medicaid for posting to web site in accordance with timeline.	Quarterly (minimum)
<b>8</b>	<b>Manufacturer Coordination</b>	Coordinate all requests for written comments and oral presentations by manufacturers for P&T meetings to include: <ul style="list-style-type: none"> <li>• receipt and review of written comments;</li> <li>• receipt and review of oral presentation summaries;</li> <li>• notification of approval/denial of submitted documents.</li> </ul> See Section B, II, D, Reporting, for a detailed listing of current documents.	Quarterly (minimum)
<b>9</b>	<b>P&amp;T Meeting Presenter</b>	Provide overview of clinical review packet information for each AHFS class reviewed to the P&T members at the Committee meetings.  This presentation must be made by a Medicaid approved professional clinical pharmacist who is fully versed with the information contained in the review and who is capable of entertaining questions from Committee members regarding findings and recommendations.	Quarterly (minimum)

10	<b>P&amp;T Meeting Minutes</b>	<p>Provide detailed minutes of P&amp;T Committee meetings so that discussion, motions, amendments, and recommendations are reflected accurately.</p> <p>Act as the recording secretary of all P&amp;T Committee meetings and provide detailed and comprehensive minutes to Medicaid within (2) two weeks after the meeting for approval.</p> <p>A final copy is to be sent to Medicaid for sign-off upon completion and must be received by Medicaid within one week of receipt of approval by Medicaid.</p>	Quarterly (minimum)
11	<b>P&amp;T Meeting Summary</b>	Provide a written summary of P&T Meeting minutes for Alabama Medicaid's Drug Utilization Review (DUR) Board. It should be a brief summary of activity and actions of the P&T Committee and provided to the designated Medicaid staff.	Quarterly (minimum)
12	<b>PDP Listings</b>	<p>Maintain all PDP lists by classes.</p> <p>Current Listings:</p> <ul style="list-style-type: none"> <li>• PDL (alphabetical)</li> <li>• PDL (categorical)</li> <li>• PDL Reference Tool (all classes)</li> <li>• PDL Reference Tool (Prenatal Vitamins) (currently maintained in house)</li> <li>• Prenatal Vitamin by NDC (currently maintained in house)</li> <li>• 1st Generation Antihistamines by NDC (currently maintained in house)</li> </ul>	Quarterly



<b>13</b>	<b>Maximum Unit List</b>	<p>Make recommendations for changes/additions to the maximum unit list using methodology approved by Medicaid. Currently, Medicaid max unit limits are applied based on FDB's GSN coding.</p> <p>Specifics:</p> <p>Make recommendations on a routine basis according to a timeline approved by Medicaid.</p> <p>New drugs identified for the max unit list must be approved by Medicaid.</p>	Quarterly
<b>14</b>	<b>Nutritional Reviews</b>	<p>Review, maintain and update nutritional listings using methodology approved by Medicaid upon request. Current Listings include:</p> <ul style="list-style-type: none"> <li>• Nutritional Products-Covered</li> <li>• Nutritional Products-Non-Covered</li> <li>• Nutritional Products-Diagnosis Grid</li> <li>• Nutritional Products-Pending</li> </ul>	Semi-annually (minimum)
<b>15</b>	<b>Prior Authorization Criteria</b>	<p>Develop, maintain, and update internal and external criteria for those drugs that fall in the scope of the PDL, as well as when requested by Medicaid for those drugs currently on prior authorization that fall outside the scope of the PDL. These documents may be based on drug class, drug, or disease. Current documents include:</p> <ul style="list-style-type: none"> <li>• Internal Prior Authorization Criteria</li> <li>• External Prior Authorization Criteria</li> <li>• External Criteria Booklet</li> </ul> <p>All criteria must be approved by Medicaid.</p>	Quarterly and upon update

<b>16</b>	<b>Clinical Appeal Response</b>	<p>Respond to clinical appeals submitted to Medicaid by manufacturer's representative as related to the reviews for P&amp;T Committee Meetings. <i>(For more information regarding the clinical appeals process, view Appendix D: Operating Procedures).</i></p> <p>It is the responsibility of the Contractor to respond to any appeals within the designated timeframe regarding information that the Contractor has presented even after the contract has expired.</p> <p>Responses should include:</p> <ul style="list-style-type: none"> <li>any concerns or issues in the appeal from the manufacturer concerning the drug, information regarding any studies or clinical information that the manufacturer has presented;</li> <li>reason why clinical information, concern and/or issue was or was not included in the review and why or why it does not change the recommendation;</li> <li>final summary paragraph needs to state if the original recommendation presented in the review should stand as is or if it needs to be amended.</li> </ul>	As Requested
<b>17</b>	<b>P&amp;T Member Term Expiration Notification</b>	Send written notification to P&T members whose terms are expiring.	Up to quarterly, rolling terms for each member
<b>18</b>	<b>P&amp;T New Member Notification</b>	Send written notification to new members selected for the P&T Committee annually or upon update.	Up to quarterly, rolling terms for each member
<b>19</b>	<b>P&amp;T Member Listing (internal &amp; external)</b>	Maintain a listing of committee members and send an electronic version to Medicaid annually or upon update.	Up to quarterly, rolling terms for each member
<b>20</b>	<b>New P&amp;T Member Orientation</b>	Conduct an orientation with all new members prior to first meeting to provide an overview of the committee. These meetings are to be conducted with a designated Medicaid staff member.	Up to quarterly, rolling terms for each member

21	<b>PDL Recommendations Report</b>	<p>Recommend classes or sub-classes of drugs to Medicaid to be included in the Preferred Drug Program.</p> <p>Provide projected cost savings for classes/sub-classes recommended for review for the PDL based on past medical claims data. Savings projections should include multiple utilization shift scenarios.</p>	Quarterly
22	<b>PDL Savings Analysis Reports</b>	Provide and maintain PDL cost effectiveness (impact assessment) report based on medical/institutional claims data.	Quarterly and Annually
23	<b>PDP Recommendations</b>	<p>Make recommendations to Medicaid regarding operational policy and procedures for the Preferred Drug Program and pharmacy program policy and procedures as they relate to the scope of work of this RFP.</p> <p>Contractor is expected to utilize its expertise in the scope of this RFP to identify procedures that may improve current Medicaid policy.</p>	Annually
24	<b>Market Share Report</b>	<p>Provide quarterly market share information regarding preferred and non-preferred drugs and their classes.</p> <p>Report Specifics:</p> <ul style="list-style-type: none"> <li>• the overall % market share of all drugs in each class;</li> <li>• x% market share of preferred products in each class;</li> <li>• x% market share of non-preferred products for each 6 digit AHFS class;</li> <li>• x% market share for the individual class as compared to all classes.</li> </ul> <p>Report to be sent electronically and one color hard copy to be mailed to Alabama Medicaid's PDL Administrator.</p>	Quarterly

25	<b>First Databank Clinical Highlights Report</b>	<p>Review FDB Clinical and Editorial highlights on a weekly basis and make recommendations to Medicaid on any needed actions.</p> <p>Provide notification to Medicaid within one calendar week of First DataBank (FDB) notification of products new to the market that fall into a classification of drugs included in the scope of the Preferred Drug List or the Prior Authorization Program, override program, or coverage/non-coverage.</p> <p>Provide recommendations to include in review for PDL, Prior Authorization Program, override program, or coverage/non-coverage.</p>	Weekly
26	<b>Ad-hoc Reports (as requested by Medicaid/Committee)</b>	<p>Recommend drugs, based on clinical information, to be considered for prior authorization, override, or coverage to Medicaid through the P&amp;T Committee or Medicaid that fall into the following categories:</p> <ul style="list-style-type: none"> <li>• Drugs with historical problems relative to physical and psychological dependency;</li> <li>• Drugs used for non-FDA approved indications or whose use is not supported by appropriately conducted and published, peer-reviewed medical research;</li> <li>• Drugs which require important diagnostic procedures be completed before the administration to</li> </ul>	Up to four times per year

		<p>maximize therapeutic benefits;</p> <ul style="list-style-type: none"> <li>• Drugs associated with special dosing, duration and/or administration requirements or considerations;</li> <li>• Drugs for which feedback is necessary to assist practitioners with treatment alternatives that may be just as effective, safe and less costly;</li> <li>• Drugs for which over-the-counter alternatives exists and are covered or could be covered by Medicaid;</li> <li>• Drugs with high cost or supply problems.</li> </ul> <p>Previous examples include:</p> <ul style="list-style-type: none"> <li>• Antipsychotics</li> <li>• Prenatal vitamins</li> <li>• Soma</li> </ul>	
		<p><u>Clinical and Utilization Research (P&amp;T)</u></p> <p>Provide clinical information and utilization data based on state and national trends in prescribing and dispensing patterns regarding the need for drugs specified by the P&amp;T Committee and/or Medicaid.</p> <ul style="list-style-type: none"> <li>• A previous example includes methadone research.</li> </ul>	As requested in conjunction with P&T Reviews
		<p><u>Projected Cost Savings</u></p> <p>Provide projected cost savings for potential edits/overrides/non-coverage for drugs and drugs classes that fall outside the scope of the PDL as requested by Medicaid.</p>	Up to quarterly

## B. Hemophilia Audit Program

Vendor must be responsible for all hemophilia auditing components and must not proceed with any audit component without prior approval from Medicaid. Additionally, a pharmacy provider may request a hearing on the audit findings. The Vendor's appropriate personnel, involved in the audit process, shall be available at Medicaid's request to provide justification in any Fair Hearings. The Vendor, in a

timely and professional manner, must provide all contract deliverables utilizing formats and time lines approved by Medicaid.

The following listing includes, but is not limited to, the responsibilities related to the hemophilia auditing component of this contract.

As a part of the proposal, the Vendor must provide a detailed description for each of the contract deliverables listed below:

	Contract Deliverables	Tasks	Deliverable Frequency
1	Provider Desk Audit	Conduct, at minimum, annual retrospective audits on providers of blood clotting factor to ensure compliance with minimum standards of care guidelines, reimbursement methodology and Medicaid and State billing and Board of Pharmacy (BOP) policy, dispensed dose assay, 24- hour call emergency support service, appropriate staff, emergency delivery of blood clotting factor.	
		<b>Audit Types</b>	
		<u>Pharmacy Providers</u>  An audit of pharmacy providers will be conducted in January of each calendar year utilizing records from the previous calendar year. Components to include, but not limited to: <ul style="list-style-type: none"> <li>• Hemophilia patient assessment and follow up;</li> <li>• Educational materials offered;</li> <li>• monthly case management follow-up;</li> <li>• quantity of blood clotting factor dispensed;</li> <li>• the amount of blood clotting factor billed and invoice pricing submitted to Alabama Medicaid;</li> <li>• review of Provider's Emergency Plan.</li> </ul>	Annually
		<u>Top Recipients</u>  An audit of top recipients will be conducted as requested by Medicaid. This audit will review records during a	Annually

		<p>specified timeframe as determined by Medicaid.</p> <ul style="list-style-type: none"> <li>Includes recipient/caregiver survey</li> </ul> <p><u>Product Recall/Withdrawal</u></p> <p>An audit will be conducted only when a known major recall of an antihemophilic factor product has occurred. This recall shall be due to a defect in the antihemophilic factor product itself and harbor the potential for recipient injury in order to qualify for recall audit procedures.</p>	As Needed
2	<b>Individual Provider Audit Reports</b>	<p>Report the outcome of each provider audit for each audit type.</p> <p>Mail copies of the final hemophilia audit reports and a cover letter to each pharmacy provider.</p> <p>Provide copies of the final hemophilia audit reports and a cover letter to designated Medicaid staff.</p>	Annually (minimum)
3	<b>Provider Audit Results Summary</b>	<p>Provide Medicaid designee with a report summarizing compliance with the Hemophilia Management Standards of Care for each pharmacy provider. Submit a summary report reviewing the findings for all pharmacy providers.</p>	Annually (minimum)
4	<b>Audited Provider Listing</b>	<p>Provide Alabama Medicaid with a listing of pharmacies to be audited per audit type.</p> <p><u>Utilize Medicaid Decision Support System (DSS) to identify:</u></p> <ul style="list-style-type: none"> <li><u>hemophilia providers to be audited;</u></li> <li><u>detailed patient specific claim information; and</u></li> <li><u>blood clotting factor reimbursement information to be used in the auditing procedures.</u></li> </ul>	Annually (minimum)

<b>5</b>	<b>Provider Audit Notification and Status Letter(s)</b>	Draft audit notification and status letter templates to be sent to potentially audited providers.	On-going
		Draft materials are to be sent to Medicaid electronically and must be approved by Medicaid.	
		A timeline for all drafts should be approved by Medicaid for each audit and must be followed by the Vendor.	
		Notify participating pharmacies of auditing procedures, to include requesting required documentation needed.	Annually (minimum)
<b>6</b>	<b>Audit Procedures Updates</b>	Draft audit procedures updates.	On-going
<b>7</b>	<b>Appropriate Clinical Staff</b>	<p>Provide a Hemophilia Audit Coordinator to conduct and oversee auditing procedures. This person shall have a deep understanding of hemophilia, blood clotting factor delivery, and prescriptions/orders for these drugs.</p> <p>The Hemophilia Audit Coordinator may also serve as the Clinical Pharmacist.</p>	On-going
<b>8</b>	<b>Fair Hearing Representation</b>	Provide Medicaid approved clinical staff to present information at fair hearing meetings held in Montgomery, AL.	Per Request
<b>9</b>	<b>Research</b>	<p>Support the continued development and operation of the Medicaid Hemophilia Audit Program by providing current clinical research.</p> <p>Provide clinical information and utilization data based on state and national trends in prescribing and dispensing patterns regarding the need for blood clotting factor specified by Medicaid.</p>	Annually (minimum)



### C. Reference Tools

In order to provide current in-depth clinical information, Vendor must acknowledge and comply that the Vendor has readily available access to, at minimum, the following:

<b><u>CD-ROM/On-line/hard copy databases</u></b>	<b><u>Medical/Pharmacy and related journals, textbooks and newsletters</u></b>
Alabama Medicaid's Decision Support System (DSS)	AHFS Drug Information
AHFS	Annals of Internal Medicine
Clinisphere/Facts & Comparisons	Annals of Pharmacotherapy
Drug Information Facts	American Journal of Managed Care
Epocrates	Clinical Infectious Diseases
FDA (Food and Drug Administration)	Clinical Microbiology Update
First DataBank	Critical Care Medicine
International Pharmaceutical Abstracts	Disease-A-Month
Mandell's Principles and Practices of Infectious Disease	Disease Management and Health Care Outcomes
Mayo Clinic Family Health Book	Drug Benefit Trends
MedLine	Drug Information Handbook
Medscape	Drug Information Journals
Micromedex	Drugs
Micromedex Redbook for Windows	Drugs and Aging
New England Journal of Medicine	Drug Safety
NIH (National Institute of Health)	Drugs and Therapy Perspectives
OVID	Facts & Comparisons

The Formulary Information Exchange	Healthcare Innovation
Patient Drug Facts	HIV/AIDS Surveillance
Physician's GenRx	Infectious Disease Alert
PubMed	Internal Medicine Alert
	JAMA
	Journal of Managed Care Pharmacy
	Journal of Outcomes Management
	Lexicomp Drug Information Handbook
	Medical Letters
	New England Journal of Medicine
	New Products Bulletin
	Pharmacist's Letter
	Prescriber's Letter

## **D. Reporting**

Vendor must acknowledge and comply that the Vendor will submit standard reports, and Medicaid may request ad-hoc reports. Standard reports include but are not limited to:

### Preferred Drug Program Specific:

- Annual PDL Cost Savings Analysis
- Quarterly PDL Savings Analyses (projected and actual)
- Quarterly PDL Recommendations
- Quarterly Market Share Report
- Weekly First Databank Clinical Highlights Reports
- Weekly Conference Call Agenda and Meeting Minutes

### P&T Meeting Specific (at minimum, quarterly):

- Pharmacological Clinical Review Packet
- P&T Meeting Minutes (public)
- P&T Meeting Minutes (DUR Board)
- Manufacturer Notification Tracking Log
- Manufacturer Written Clinical Comments Tracking Log
- Manufacturer Oral Presentations Tracking Log
- Accepted Oral Presentation and Written Clinical Comments Listing
- Oral Presentations by Drug Class Listing
- Committee Member Attendance Log
- Manufacturer Clinical Appeals Tracking Log

### Clinical Support Specific:

- Maximum Units Listings
- Nutritional Products Listings
- Prior Authorization Criteria

### Hemophilia Audit Specific:

- Provider Audit Notifications
- Individual Provider Audit Reports
- Provider Audit Results Summary for AL Medicaid
- Top 10 Recipient Users (product and cost amounts)
- Pharmacy Providers (product and cost amounts)

## **E. Additional Vendor Responsibilities**

Vendor must acknowledge and comply that the Vendor will be expected to perform

all responsibilities and deliverables within this RFP. Vendor must coordinate with the Medicaid Project Manager throughout the term of this contract for any questions and further direction as it relates to the functions of this RFP. Additional Vendor responsibilities are listed below:

- Provide staff who are available to respond to Medicaid requests in a timely manner. It is expected that all telephone calls, emails, and faxes from Medicaid must be responded to within one business day. All requests for information are to be delivered within the timeframe established by Medicaid in coordination with Vendor.
- Provide clinical information and respond to questions from Medicaid designated Pharmacy staff in a timely and professional manner.
- Notify Medicaid in advance if designated Vendor staff will be unavailable or out of the office. A qualified alternate contact is to be designated.
- Provide designated staff to participate in Medicaid/Vendor meetings/conference calls as scheduled by Medicaid in coordination with Vendor.
- Adhere to Medicaid policies for meetings and communications with pharmaceutical industry representatives to include but not limited to those detailed in Attachment J regarding issues contained in the Scope of Work of this RFP.
- Make recommendations for changes to existing criteria across all programs based on clinical data from approved peer review literature. Recommendations shall also include the addition of new procedures, services, or equipment for approval to increase efficiency, program effectiveness, and appropriate utilization as it relates to this RFP.
- Make Vendor clinical personnel available to participate in informal reviews and hearings resulting from provider or manufacturer appeals.

**a. Informal Review**

An Aggrieved Party may request reconsideration of an adverse decision through the informal review process by filing a written request with the selected Vendor within 15 business days of the date of the denial letter. Upon receipt of a reconsideration request, the selected Vendor shall review the documentation and render a decision based on Medicaid-approved criteria within 10 business days of receipt of a complete reconsideration request. The selected Vendor shall mail notice of the reconsideration decision to the Aggrieved

Party.

**b. Fair Hearing**

An Aggrieved Party may request a Fair Hearing by filing a written request with the Medicaid Administrative Hearings Office within 60 calendar days of the date of the reconsideration denial notice by the selected Vendor. The selected Vendor's consulting and other appropriate personnel who were involved in the denial shall be available at Medicaid's request Monday through Friday, from 8:00 am to 5:00 pm, to provide justification for the denial and participate in any Fair Hearings as scheduled by Medicaid.

**c. Manufacturer Appeals/Reconsiderations**

Manufacturers may request a reconsideration of a clinical recommendation of the P&T Committee if there is new clinical evidence-based, peer reviewed information to consider that was not presented during the P&T review. A written request must be submitted to the Medicaid Pharmacy Director or designated representative and must be received within thirty (30) calendar days of the posting of the PDL decisions to the Medicaid website. A request must meet the following criteria: 1. be submitted via email, PDF format only, not hard copy or CD-Rom, etc., 2. be clearly labeled as a Clinical Reconsideration Request, 3. include new clinical evidence-based information to consider that was not presented during the P&T review, and 4. include manufacturer contact information. Vendor will respond in writing, upon approval by Medicaid, to all appeals within ninety (90) calendar days of receipt. Responses will be sent via US Mail.

- Provide quarterly reports identifying projected and actual cost savings associated with the Preferred Drug Program.
- Make recommendations to Medicaid for provider education and outreach as it relates to information and data obtained from requesting providers.

**F. Operational Requirements**

Vendor must acknowledge and comply that the Vendor will be responsible for entering and/or interfacing with Medicaid's Decision Support System (DSS) for utilization and pricing data.

Vendor must acknowledge and comply that the Vendor will be responsible for providing a site to site private network (VPN) connection between the Vendor and Medicaid's Fiscal Agent. The charge for this service will be paid by the Vendor. Medicaid Vendor is required to provide a suitably sized ISP and VPN hardware to

support the Vendor's network. The Vendor must complete the Site To Site VPN Technical Specifications document furnished by Gainwell Technology to provide the necessary technical information for the establishment of the tunnel.

Alabama Medicaid Management and Information System (AMMIS) passwords will be made available by Medicaid's fiscal agent for Vendor employees.

Vendor responsibilities include:

1. Submission of requests for employee passwords for the Medicaid system to Medicaid
2. Notifying Medicaid when an issued password is no longer needed due to termination of employment or change in duties
3. Ensuring that its employees are informed of importance of system security and confidentiality
4. Documenting and notifying Medicaid of system problems to include type of problem, action(s) taken by Vendor to resolve problem and length of system down-time within eight hours of problem identification. Vendor must ensure that problem is resolved within 72 hours of system down time.

Medicaid will:

1. Obtain security passwords from the Fiscal Agent upon Vendor request
2. Serve as liaison between Vendor and Fiscal Agent

Vendor must have a HIPAA-compliant system with effective security measures to prevent the unauthorized use of, or access to, data. The selected Vendor must maintain confidentiality and only use information from Medicaid to fulfill its contractual obligations regarding utilization data.

Vendor hereby certifies that any exchange of AMMIS data with Medicaid's fiscal agent will be accomplished by following the Alabama Medicaid Vendor Interface Specifications, which will be posted on the Medicaid website.

## **G. Key Personnel**

The Vendor must have in place the necessary personnel to perform all duties and responsibilities outlined in this RFP. At a minimum, a Project Manager, a full-time Clinical Pharmacist and a Hemophilia Audit Coordinator must be named. It is acceptable for the Project Manager and/or the Hemophilia Audit Coordinator to be the named Clinical Pharmacist.

Medicaid will have the absolute right to approve or disapprove Vendor's and any subvendor's staff or to require the removal or reassignment of any personnel found by Medicaid to be unwilling or unable to perform under the terms of the contract. Vendor must, upon request, provide Medicaid with a resume/CV of any

member(s) of its staff or a subvendor's staff assigned to or proposed to be assigned to any aspect of the performance of this contract. Personnel commitments made on Vendor's response must not be changed except as herein above provided or due to the resignation of any named individual. Any personnel of a clinical nature (i.e. pharmacist, physician, nurse, technician, etc.) must have a current license and be in good standing with their respective appropriate state board and cannot be involved in pharmaceutical detailing activities for any pharmaceutical company.

The Vendor's key personnel must include the following positions:

**a. Project Manager**

Vendor must assign to the Alabama Medicaid Agency a Project Manager with a minimum of an Undergraduate Degree. The Project Manager must be the person assigned under this contract, who is responsible for operation of contract duties.

Vendor's Project Manager must:

- serve as liaison and be available and responsible, as the need arises, for consultation and assistance with Medicaid personnel;
- attend, upon request, Medicaid meetings, administrative hearings, meetings and hearings of Legislative Committees and interested governmental bodies, agencies, and officers; and
- provide timely and informed responses when operational and administrative issues arise in administration of the Alabama Medicaid Program.

Whenever the Project Manager is not reasonably available, Vendor must provide a designated alternate fully capable of meeting the requirements of this section.

**b. Clinical Pharmacist**

Vendor must assign a full-time Clinical Pharmacist with a minimum of a Doctor of Pharmacy degree to the Alabama Medicaid Agency contract. This person must have a current license and be in good standing with the appropriate State Board of Pharmacy. The Clinical Pharmacist must be the person assigned under this contract, who is responsible for the clinical components of the contract duties. The Clinical Pharmacist must possess superior clinical and administrative competence and demonstrate proficiency in drug therapy management.

Vendor's Clinical Pharmacist must:

- serve as clinical resource and be available and responsible, as

- the need arises, for consultation and assistance with Medicaid personnel;
- attend, upon request, meetings relevant to the scope of work in this RFP to include all meetings of the Pharmacy and Therapeutics Committee; and
- provide timely and informed responses when operational and administrative issues arise in administration of the Alabama Medicaid Program.

Whenever the Clinical Pharmacist is not reasonably available, Vendor must provide a designated alternate fully capable of meeting the requirements of this section.

### **c. Hemophilia Audit Coordinator**

Vendor must assign a full-time Hemophilia Audit Coordinator who may serve as the Clinical Pharmacist. The Hemophilia Audit Coordinator shall have an understanding of hemophilia bloodfactor dosing, percent assay variance, and general audit procedures. Upon contract award, the Hemophilia Audit Coordinator will become familiar with the Alabama Hemophilia Standard of Care.

Vendor's Hemophilia Audit Coordinator must:

- serve as liaison and be available and responsible, as the need arises, for consultation and assistance with Medicaid personnel;
- attend, upon request, Medicaid meetings, administrative hearings, and provider meetings relevant to the scope of work in this RFP related to the hemophilia audit program; and
- provide timely and informed responses when operational and administrative issues arise in administration of the Alabama Medicaid Program.

### **Good Faith Effort**

The Vendor must make a good faith effort to use the same Project Manager, Clinical Pharmacist and Hemophilia Audit Coordinator throughout the contract. Vendor must notify Medicaid in writing of any proposed change in Project Manager at least 30 days prior to the change. Vendor must notify Medicaid immediately of any extenuating circumstances which would prevent Vendor from meeting the 30-day notification time frame.

### **Resume/Curriculum Vitae**

Vendor must furnish the following with its response to the RFP for the proposed Project Manager, Clinical Pharmacist and Hemophilia Audit Coordinator positions:



1. A resume/CV to include the following:
  - individual's name;
  - current address;
  - current title and position;
  - experience with Vendor;
  - current standing with his/her respective Board of Pharmacy;
  - experience in performing relevant functions, both clinical and administrative;
  - relevant education, training, and management experience; and
2. Two work references.

## **H. Other Personnel**

Vendor must demonstrate the ability to secure and retain professional staff to meet contract requirements. This must include, but is not limited to,

1. Staff member with a financial-based education (accounting, statistics, business degree, etc.) for projected cost savings data; and
2. Other clinical (to include experts in specific drug class areas of respected review, i.e. mental health drugs, diabetic agents, etc.) and administrative personnel to carry out the requirements of this contract. For example, a previous Vendor had an expert in the field of behavioral health medication therapy who was instrumental in developing and presenting the clinical review for those specific AHFS classes.

The proposal response must clearly outline Vendor's plan to address the personnel requests of this RFP.

Medicaid will have the absolute right to approve or disapprove Vendor's and any subvendor's project manager, consulting physicians, physical therapists, registered nurses and/or provider representatives assigned to the contract, to approve or disapprove any proposed changes in this personnel, or to require the removal or reassignment of any personnel found by Medicaid to be unwilling or unable to perform under the terms of the contract. Vendor must, upon request, provide Medicaid with a resume/CV of any members of its staff or a subvendor's staff assigned to or proposed to be assigned to any aspect of the performance of this contract. Personnel commitments made in Vendor's response must not be changed except as herein above provided or due to the resignation of any named individual.

## **I. Organizational Plan**

Vendor must submit an organizational chart to Medicaid for approval prior to contract implementation. This plan must include a breakdown of job duties and responsibilities of management staff. Any subsequent changes to the organizational

plan must be approved by Medicaid.

Vendor may assign one individual for Program Manager and the Clinical Pharmacist as long as the individual is qualified to perform duties outlined for these positions and all contract requirements are met.

## **J. Work Plan and Implementation Schedule**

Vendor must provide a proposed work plan and implementation schedule as a part of this RFP response submission. A revised work plan and implementation schedule must be provided to Medicaid in electronic format within 30 business days of contract award.

The work plan must identify major tasks, the work elements of each task, the resources assigned to the task, the time allotted to each element and the deliverable items the selected Vendor will produce.

## **K. Medicaid Responsibilities**

Medicaid will be expected to follow the additional Medicaid responsibilities below:

- Correspond to inquiries from the Vendor in a timely and accurate manner interpreting Medicaid policy so that Vendor is able to respond and provide deliverables as indicated throughout this RFP.
- Provide Vendor with policies for meeting/communication with pharmaceutical industry representatives.
- Provide instruction to Vendor regarding P&T Committee operational procedures and policies.
- Schedule Vendor/Medicaid meetings in coordination with Vendor as needed. These meetings may be held via weekly teleconference unless specified in advance by Medicaid.
- Respond to Vendor requests for information in a timely and professional manner.
- Provide staff responsible for working with Vendor on assignments and requests.
- Post the maximum quantity listing on the website.
- Provide instruction to Vendor regarding requests for research or recommendations as detailed in the Scope of Work.
- Review and approval of P&T meeting minutes and meeting materials in a timely manner.
- Post meeting notices, clinical reviews, P&T policies and procedures,

recommendations of the P&T Committee, Final PDL documents, PDL listings and P&T member listings to the Medicaid web site.

- Provide meeting locations for the P&T Committee meeting.
- Provide Vendor with a final listing of drugs to be included in clinical reviews as described in this RFP.
- Maintain all administrative authority over the Medicaid Pharmacy Program.
- Notify Vendor in writing of any concerns regarding Vendor's performance.

## **L. Monitoring Performance Standards and Corrective Action Plans**

Medicaid will monitor the Vendor's performance according to the requirements contained within this RFP.

Medicaid will inform Vendor when performance does not comply with the contract requirements and of any cost associated/liquidated damage assessments. Vendor must prepare and submit for approval a corrective action plan for each identified problem within the timeframe determined by Medicaid. The corrective action plan must include, but is not limited to:

- a. Brief description of the findings.
- b. Specific steps the selected Vendor will take to correct the situation or reasons why the selected Vendor believes corrective action is not necessary.
- c. Name(s) and title(s) of responsible staff person(s).
- d. Timetable for performance of each corrective action step.
- e. Signature of a senior executive.

Vendor must implement the corrective action plan within the timeframe specified by Medicaid. Failure by the selected Vendor to implement corrective action plans, as required by Medicaid, may result in further action by Medicaid.

## **M. Damages for Cost Associated with Breach of Contract/Liquidated Damages**

The Vendor's proposal must acknowledge and comply with the following requirements:

In the event that Vendor fails to meet the requirements of this RFP and contract requirements, Medicaid will recover damages for cost associated with breach of contract. Vendor agrees to pay Medicaid the sums set forth below unless waived by Medicaid.

- a. Failure to deliver requisite reports/services/deliverables as

defined by the RFP by the date specified by Medicaid - \$100 per day per report/deliverable.

- Examples include, but are not limited to:
  - PDP listings
  - Maximum unit list
  - Responding to clinical appeal(s)
  - Projected cost savings and drug lists by AHFS class
  - Determination and identification of brand versus generic or OTC versus legend drugs
- b. Failure to include Medicaid requested changes/corrections/revisions in deliverables as required by the RFP - \$100 per instance per document.
- c. Failure to comply with any other requirement of the RFP, - \$1000 per instance.
  - Examples include but are not limited to:
    - failure to be punctual for P&T Committee meetings,
    - failure to notify manufacturers and/or P&T Committee members of upcoming meetings
    - failure to mail clinical review packets to Medicaid Agency and/or P&T Committee members
- d. Failure to submit an acceptable required corrective action plan - \$1000 per instance.
- e. Failure to perform tasks as specified in the RFP within the time specified by Medicaid - \$100 per day.
  - Examples include, but are not limited to:
    - P&T minutes timelines
    - P&T Clinical Packet Review timelines
- f. Use of materials without prior review or approval by Medicaid - \$2,500 per instance.
  - Examples include, but are not limited to:
    - internal/external criteria
    - P&T Clinical Review Packets
- g. Failure to maintain adequate staffing levels necessary to perform the requirements of the RFP - \$1,000 per instance.
- h. Misrepresentation or falsification of information furnished to the State - \$1,000 per instance.
- i. Presentations to groups/associations or others regarding this contract and related

work without prior approval of Medicaid - \$2,500 per instance

- j. Failure to comply with meeting and communication policy (Attachment J) involving the pharmaceutical industry as provided by Medicaid - \$2,500 per instance
- k. Failure to meet technical requirements - \$100 per day that requirement is not met.

In addition:

- l. Imposition of cost associated with breach of contract/liquidated damages may be in addition to other contract remedies and does not waive Medicaid's right to terminate the contract.
- m. Unauthorized use of information shall be subject to the imposition of cost associated with breach of contract /liquidated damages in the amount of ten thousand dollars (\$10,000) per instance.
- n. Failure to safeguard confidential information of providers, recipients or the Medicaid program shall be subject to the imposition of \$10,000 per instance plus any penalties incurred by Medicaid for said infractions.

Vendor must receive written notice from Medicaid upon a finding of failure to comply with contract requirements, which contains a description of the events that resulted in such a finding. Vendor must be allowed to submit rebuttal information or testimony in opposition to such findings. Medicaid will make a final decision regarding implementation of cost associated with breach of contract/liquidated damages.

### **III. Pricing**

Vendor's response must specify a firm and fixed fee for all aspects of this RFP. The Firm and Fixed Price of each year must be stated in the RFP Cover Sheet on the first page of this document and Appendix C.

### **IV. General Medicaid Information**

The Alabama Medicaid Agency is responsible for the administration of the Alabama Medicaid Program under a federally approved State Plan for Medical Assistance. Through teamwork, the Agency strives to enhance and operate a cost efficient system of payment for health care services rendered to low income individuals through a partnership with health care providers and other health care insurers both public and private.

Medicaid's central office is located at 501 Dexter Avenue in Montgomery, Alabama. Central office personnel are responsible for data processing, program management, financial management,

program integrity, general support services, professional services, and recipient eligibility services. For certain recipient categories, eligibility determination is made by Agency personnel located in eleven (11) district offices throughout the state and by one hundred forty (140) out-stationed workers in designated hospitals, health departments and clinics. Medicaid eligibility is also determined through established policies by the Alabama Department of Human Resources and the Social Security Administration. The Alabama Medicaid Agency serves approximately 1,000,000 Alabama citizens each year through a variety of programs.

Services covered by Medicaid include, but are not limited to, the following:

- Physician Services
- Inpatient and Outpatient Hospital Services
- Rural Health Clinic Services
- Laboratory and X-ray Services
- Nursing Home Services
- Early and Periodic Screening, Diagnosis and Treatment
- Dental for children ages zero (0) to twenty (20)
- Home Health Care Services and Durable Medical Equipment
- Family Planning Services
- Nurse-Midwife Services
- Federally Qualified Health Center Services
- Hospice Services
- Prescription Drugs
- Optometric Services
- Transportation Services
- Hearing Aids
- Intermediate Care Facilities for Individuals with Intellectual Disabilities
- Prosthetic Devices
- Outpatient Surgical Services
- Renal Dialysis Services
- Home and Community Based Waiver Services
- Prenatal Clinic Services
- Mental Health Services

Additional program information can be found at [www.medicaid.alabama.gov](http://www.medicaid.alabama.gov).

## **V. General**

This document outlines the qualifications which must be met in order for an entity to serve as Contractor. It is imperative that potential Contractors describe, **in detail**, how they intend to approach the Scope of Work specified in Section II of the RFP. The ability to perform these services must be carefully documented, even if the Contractor has been or is currently participating in a Medicaid Program. Proposals will be evaluated based on the written information that is presented in the response. This requirement underscores the importance and the necessity of providing in-depth information in the proposal with all supporting documentation necessary.

The Vendor must demonstrate in the proposal a thorough working knowledge of program policy requirements as described, herein, including but not limited to the applicable Operational Manuals,

State Plan for Medical Assistance, Administrative Code and Code of Federal Regulations (CFR) requirements.

Entities that are currently excluded under federal and/or state laws from participation in Medicare/Medicaid or any State's health care programs are prohibited from submitting bids.

## **VI. Corporate Background and References**

### **Entities submitting proposals must:**

- a. Provide evidence that the Vendor possesses the qualifications required in this RFP.
- b. Provide a description of the Vendor's organization, including
  1. Date established.
  2. Ownership (public company, partnership, subsidiary, etc.). Include an organizational chart depicting the Vendor's organization in relation to any parent, subsidiary or related organization.
  3. Number of employees and resources.
  4. Names and resumes of Senior Managers and Partners in regards to this contract.
  5. A list of all similar projects the Vendor has completed within the last three years.
  6. A detailed breakdown of proposed staffing for this project, including names and education background of all employees that will be assigned to this project.
  7. A list of all Medicaid agencies or other entities for which the Vendor currently performs similar work.
  8. Evidence that the Vendor is financially stable and that it has the necessary infrastructure to complete this contract as described in the Vendor's Proposal. The Vendor must provide audited financial statements for the last three years, or similar evidence of financial stability for the last three years.
  9. Vendor's acknowledgment that the State will not reimburse the Contractor until:  
(a) the Project Director has approved the invoice; and (b) the Agency has received and approved all deliverables covered by the invoice.
  10. Details of any pertinent judgment, criminal conviction, investigation or litigation pending against the Vendor or any of its officers, directors, employees, agents or subcontractors of which the Vendor has knowledge, or a statement that there are none. The Agency reserves the right to reject a proposal solely on the basis of this information.
- c. Have all necessary business licenses, registrations, and professional certifications at the time of the contracting to be able to do business in Alabama. Alabama law provides that a foreign corporation (a business corporation incorporated under a law other than the law of this state) may not transact business in the state of Alabama until it obtains a Certificate of Authority from the Secretary of State. To obtain forms for a Certificate of Authority, contact the Secretary of State, (334) 242-5324, [www.sos.state.al.us](http://www.sos.state.al.us). The Certificate of Authority or a letter/form showing application has been made for a Certificate of Authority must be submitted with the bid.
- d. Have proven two years experience in implementing and maintaining clinical support services

for a Pharmacy program, with one of those years of experience being with a state Medicaid pharmacy program and have been in business a minimum of three years.

- e. Furnish three (3) references for projects of similar size and scope, including contact name, title, telephone number, and address. Performance references should also include contract type, size, and duration of services rendered. **You may not use any Alabama Medicaid Agency personnel as a reference.**

The State reserves the right to use any information or additional references deemed necessary to establish the ability of the Vendor to perform the conditions of the contract.

## VII. Submission Requirements

### A. Authority

This RFP is issued under the authority of Section 41-16-72 of the Alabama Code and 45 CFR part 75. The RFP process is a procurement option allowing the award to be based on stated evaluation criteria. The RFP states the relative importance of all evaluation criteria. No other evaluation criteria, other than as outlined in the RFP, will be used.

In accordance with 45 CFR part 75, the State encourages free and open competition among Vendors. Whenever possible, the State will design specifications, proposal requests, and conditions to accomplish this objective, consistent with the necessity to satisfy the State's need to procure technically sound, cost-effective services and supplies.

### B. Single Point of Contact

From the date this RFP is issued until a Vendor is selected and the selection is announced by the Project Director, all communication must be directed to the Project Director in charge of this solicitation. **Vendors or their representatives must not communicate with any State staff or officials regarding this procurement with the exception of the Project Director.** Any unauthorized contact may disqualify the Vendor from further consideration. Contact information for the single point of contact is as follows:

<i>Project Director:</i>	<b>Amanda Singletary</b>
<i>Address:</i>	<b>Alabama Medicaid Agency Lurleen B. Wallace Bldg. 501 Dexter Avenue PO Box 5624 Montgomery, Alabama 36103-5624</b>
<i>E-Mail Address:</i>	<b>PharmacyRFP@medicaid.alabama.gov</b>

### C. RFP Documentation

All documents and updates to the RFP including, but not limited to, the actual RFP, questions and answers, addenda, etc., will be posted to the Agency's website at [www.medicaid.alabama.gov](http://www.medicaid.alabama.gov).



#### **D. Questions Regarding the RFP**

Vendors with questions requiring clarification or interpretation of any section within this RFP must submit questions and receive formal, written replies from the State. Each question must be submitted to the Project Director via email. Questions and answers will be posted on the website as available.

#### **E. Acceptance of Standard Terms and Conditions**

Vendor must submit a statement stating that the Vendor has an understanding of and will comply with the terms and conditions as set out in this RFP. Additions or exceptions to the standard terms and conditions are not allowed.

#### **F. Adherence to Specifications and Requirements**

Vendor must submit a statement stating that the Vendor has an understanding of and will comply with the specifications and requirements described in this RFP.

#### **G. Order of Precedence**

In the event of inconsistencies or contradictions between language contained in the RFP and a Vendor's response, the language contained in the RFP will prevail. Should the State issue addenda to the original RFP, then said addenda, being more recently issued, would prevail against both the original RFP and the Vendor's proposal in the event of an inconsistency, ambiguity, or conflict.

#### **H. Vendor's Signature**

The proposal must be accompanied by the RFP Cover Sheet signed in ink by an individual authorized to legally bind the Vendor. The Vendor's signature on a proposal in response to this RFP guarantees that the offer has been established without collusion and without effort to preclude the State from obtaining the best possible supply or service. Proof of authority of the person signing the RFP response must be furnished upon request.

#### **I. Offer in Effect for 90 Days**

A proposal may not be modified, withdrawn or canceled by the Vendor for a 90-day period following the deadline for proposal submission as defined in the Schedule of Events, or receipt of best and final offer, if required, and Vendor so agrees in submitting the proposal.

#### **J. State Not Responsible for Preparation Costs**

The costs for developing and delivering responses to this RFP and any subsequent presentations of the proposal as requested by the State are entirely the responsibility of the Vendor. The State is not liable for any expense incurred by the Vendor in the preparation and presentation of their proposal or any other costs incurred by the Vendor prior to execution of a contract.

#### **K. State's Rights Reserved**

While the State has every intention to award a contract as a result of this RFP, issuance of the RFP in no way constitutes a commitment by the State to award and execute a contract. Upon a determination such actions would be in its best interest, the State, in its sole discretion, reserves the right to:

- Cancel or terminate this RFP;
- Reject any or all of the proposals submitted in response to this RFP;

- Change its decision with respect to the selection and to select another proposal;
- Waive any minor irregularity in an otherwise valid proposal which would not jeopardize the overall program and to award a contract on the basis of such a waiver (minor irregularities are those which will not have a significant adverse effect on overall project cost or performance);
- Negotiate with any Vendor whose proposal is within the competitive range with respect to technical plan and cost;
- Adopt to its use all, or any part, of a Vendor's proposal and to use any idea or all ideas presented in a proposal;
- Amend the RFP (amendments to the RFP will be made by written addendum issued by the State and will be posted on the RFP website);
- Not award any contract.

#### **L. Price**

Vendors must respond to this RFP by utilizing the RFP Cover Sheet to indicate the firm and fixed price for the implementation and updating/operation phase to complete the scope of work.

#### **M. E-Verify Memorandum of Understanding**

The proposal response must include an E-Verify Memorandum of Understanding with the Department of Homeland Security.

#### **N. Proposal Format**

Proposals must be prepared on standard 8 ½" x 11" paper and must be bound. All proposal pages must be numbered unless specified otherwise. All responses, as well as, any reference material presented, must be written in English.

Proposals must not include references to information located elsewhere, such as Internet websites. Information or materials presented by the Vendor outside the formal response or subsequent discussion/negotiation, if requested, will not be considered, and will have no bearing on any award.

This RFP and its attachments are available on Medicaid's website. The Vendor acknowledges and accepts full responsibility to ensure that no changes are made to the RFP. In the event of inconsistencies or contradictions between language contained in the RFP and a Vendor's response, the language contained in the RFP will prevail. Should Medicaid issue addenda to the original RFP, then said addenda, being more recently issued, would prevail against both the original RFP and the Vendor's proposal.

#### **O. Proposal Withdrawal**

The Vendor may withdraw a submitted proposal at any time before the deadline for submission. To withdraw a proposal, the Vendor must submit a written request, signed by a Vendor's representative authorized to sign the resulting contract, to the RFP Project Director. After withdrawing a previously submitted proposal, the Vendor may submit another proposal at any time up to the deadline for submitting proposals.

## **P. Proposal Amendment**

Medicaid will not accept any amendments, revisions, or alterations to proposals after the deadline for submitting proposals unless such is formally requested, in writing, by Medicaid.

## **Q. Proposal Errors**

The Vendor is liable for all errors or omissions contained in their proposals. The Vendor will not be allowed to alter proposal documents after the deadline for submitting proposals. If the Vendor needs to change a previously submitted proposal, the Vendor must withdraw the entire proposal and may submit the corrected proposal before the deadline for submitting proposals.

## **R. Disclosure of Proposal Contents**

Proposals and supporting documents are kept confidential until the evaluation process is complete and a Vendor has been selected. The Vendor should be aware that any information in a proposal may be subject to disclosure and/or reproduction under Alabama law. Designation as proprietary or confidential may not protect any materials included within the proposal from disclosure if required by law. The Vendor should mark or otherwise designate any material that it feels is proprietary or otherwise confidential by labeling the page as "CONFIDENTIAL". The Vendor must also state any legal authority as to why that material should not be subject to public disclosure under Alabama open records law and is marked as Proprietary Information. By way of illustration but not limitation, "Proprietary Information" may include trade secrets, inventions, mask works, ideas, processes, formulas, source and object codes, data, programs, other works of authorship, know-how, improvements, discoveries, developments, designs and techniques.

Information contained in the Pricing Section may not be marked confidential. It is the sole responsibility of the Vendor to indicate information that is to remain confidential. Medicaid assumes no liability for the disclosure of information not identified by the Vendor as confidential. If the Vendor identifies its entire proposal as confidential, Medicaid may deem the proposal as non-compliant and may reject it.

## **S. Submission of Proposals**

Proposals must be sealed and labeled on the outside of the package to clearly indicate that they are in response to 2021- Pharmacy-01. Proposals must be sent to the attention of the Project Director and received at the Agency as specified in the Schedule of Events. It is the responsibility of the Vendor to ensure receipt of the Proposal by the deadline specified in the Schedule of Events.

## **T. Copies Required**

Vendors must submit one original Proposal with original signatures in ink, one additional hard copy in binder form, plus two electronic copies of the Proposal on CD/DVD or jump drive clearly labeled with the Vendor name. One electronic copy (Word and searchable PDF format) MUST be a complete version of the Vendor's response and the second electronic (searchable PDF format) copy MUST have any information asserted as confidential or proprietary removed. Vendor must identify the original hard copy clearly on the outside of the proposal.

## **U. Late Proposals**

*Regardless of cause, late proposals will not be accepted and will automatically be disqualified from further consideration.* It shall be the Vendor's sole risk to assure delivery at the Agency by the designated deadline. Late proposals will not be opened and may be returned to the Vendor at the expense of the Vendor or destroyed if requested.

## **V. Proposal Clarifications**

The Agency reserves the right to request clarifications with any or all Vendors if they are necessary to properly clarify compliance with the requirements of this RFP. The Agency will not be liable for any costs associated with such clarifications. The purpose of any such clarifications will be to ensure full understanding of the proposal. Clarifications will be limited to specific sections of the proposal identified by Medicaid. If clarifications are requested, the Vendor must put such clarifications in writing within the specified time frame.

# **VIII. Evaluation and Selection Process**

## **A. Initial Classification of Proposals as Responsive or Non-responsive**

All proposals will initially be classified as either "responsive" or "non-responsive." Proposals may be found non-responsive at any time during the evaluation process or contract negotiation if any of the required information is not provided; or the proposal is not within the plans and specifications described and required in the RFP. If a proposal is found to be non-responsive, it will not be considered further.

Proposals failing to demonstrate that the Vendor meets the mandatory requirements listed in Appendix A will be deemed non-responsive and not considered further in the evaluation process (and thereby rejected).

## **B. Determination of Responsibility**

The Project Director will determine whether a Vendor has met the standards of responsibility. In determining responsibility, the Project Director may consider factors such as, but not limited to, the vendor's specialized expertise, ability to perform the work, experience and past performance. Such a determination may be made at any time during the evaluation process and through contract negotiation if information surfaces that would result in a determination of non-responsibility. If a Vendor is found non-responsible, a written determination will be made a part of the procurement file and mailed to the affected Vendor.

## **C. Opportunity for Additional Information**

The State reserves the right to contact any Vendor submitting a proposal for the purpose of clarifying issues in that Vendor's proposal. Vendors should clearly designate in their proposal a point-of-contact for questions or issues that arise in the State's review of a Vendor's proposal.

## **D. Evaluation Committee**

An Evaluation Committee appointed by the Project Director will read the proposals, conduct corporate and personal reference checks, score the proposals, and make a written recommendation

to the Commissioner of the Alabama Medicaid Agency. The State may change the size or composition of the committee during the review in response to exigent circumstances.

### **E. Scoring**

The Evaluation Committee will score the proposals using the scoring system shown in the table below. The highest score that can be awarded to any proposal is 100 points.

<b>Evaluation Factor</b>	<b>Highest Possible Score</b>
Corporate Background	10
References	10
Scope of Work	30
Key Personnel	10
Price	40
<b>Total</b>	<b>100</b>

### **F. Determination of Successful Proposal**

The Vendor whose proposal is determined to be in the best interest of the State will be recommended as the successful Contractor. The Project Director will forward this Vendor's proposal through the supervisory chain to the Commissioner, with documentation to justify the Committee's recommendation.

When the final approval is received, the State will notify the selected Vendor. If the State rejects all proposals, it will notify all Vendors. The State will post the award on the Agency website at [www.medicaid.alabama.gov](http://www.medicaid.alabama.gov). The award will be posted under the applicable RFP number.

## **IX. General Terms and Conditions**

### **A. General**

This RFP and Contractor's response thereto shall be incorporated into a contract by the execution of a formal agreement. The contract and amendments, if any, are subject to approval by the Governor of the State of Alabama.

The contract shall include the following:

1. Executed contract,
2. RFP, attachments, and any amendments thereto,
3. Contractor's response to the RFP, and shall be construed in accordance with and in the order of the applicable provisions of:
  - Title XIX of the Social Security Act, as amended and regulations promulgated hereunder by HHS and any other applicable federal statutes and regulations
  - The statutory and case law of the State of Alabama
  - The Alabama State Plan for Medical Assistance under Title XIX of the Social Security Act, as amended
  - The Medicaid Administrative Code
  - Medicaid's written response to prospective Vendor questions

## **B. Compliance with State and Federal Regulations**

Contractor shall perform all services under the contract in accordance with applicable federal and state statutes and regulations. Medicaid retains full operational and administrative authority and responsibility over the Alabama Medicaid Program in accordance with the requirements of the federal statutes and regulations as the same may be amended from time to time.

## **C. Term of Contract**

The initial contract term shall be for one year effective July 1, 2022, through June 30, 2023. Alabama Medicaid shall have four, one-year options for extending this contract if approved by the Legislative Contract Review Oversight Committee. At the end of the contract period Alabama Medicaid may at its discretion, exercise the extension option and allow the period of performance to be extended at the rate indicated on the RFP Cover Sheet. The Vendor will provide pricing for each year of the contract, including any extensions.

Contractor acknowledges and understands that this contract is not effective until it has received all requisite state government approvals and Contractor shall not begin performing work under this contract until notified to do so by Medicaid. Contractor is entitled to no compensation for work performed prior to the effective date of this contract.

## **D. Contract Amendments**

No alteration or variation of the terms of the contract shall be valid unless made in writing and duly signed by the parties thereto. The contract may be amended by written agreement duly executed by the parties. Every such amendment shall specify the date its provisions shall be effective as agreed to by the parties.

The contract shall be deemed to include all applicable provisions of the State Plan and of all state and federal laws and regulations applicable to the Alabama Medicaid Program, as they may be amended. In the event of any substantial change in such Plan, laws, or regulations, that materially affects the operation of the Alabama Medicaid Program or the costs of administering such Program, either party, after written notice and before performance of any related work, may apply in writing to the other for an equitable adjustment in compensation caused by such substantial change.

## **E. Confidentiality**

Contractor shall treat all information, and in particular information relating to individuals that is obtained by or through its performance under the contract, as confidential information to the extent confidential treatment is provided under State and Federal laws including 45 CFR §160.101 – 164.534. Contractor shall not use any information so obtained in any manner except as necessary for the proper discharge of its obligations and rights under this contract.

Contractor shall ensure safeguards that restrict the use or disclosure of information concerning individuals to purposes directly connected with the administration of the Plan in accordance with 42 CFR Part 431, Subpart F, as specified in 42 CFR § 434.6(a)(8). Purposes directly related to the Plan administration include:

1. Establishing eligibility;
2. Determining the amount of medical assistance;

3. Providing services for recipients; and
4. Conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the administration of the Plan.

Pursuant to requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Public Law 104-191), the successful Contractor shall sign and comply with the terms of a Business Associate agreement with the Agency (Appendix B).

#### **F. Security and Release of Information**

Contractor shall take all reasonable precautions to ensure the safety and security of all information, data, procedures, methods, and funds involved in the performance under the contract, and shall require the same from all employees so involved. Contractor shall not release any data or other information relating to the Alabama Medicaid Program without prior written consent of Medicaid. This provision covers both general summary data as well as detailed, specific data. Contractor shall not be entitled to use of Alabama Medicaid Program data in its other business dealings without prior written consent of Medicaid. All requests for program data shall be referred to Medicaid for response by the Commissioner only.

#### **G. Federal Nondisclosure Requirements**

Each officer or employee of any person to whom Social Security information is or may be disclosed shall be notified in writing by such person that Social Security information disclosed to such officer or employee can be only used for authorized purposes and to that extent and any other unauthorized use herein constitutes a felony punishable upon conviction by a fine of as much as \$5,000 or imprisonment for as long as five years, or both, together with the cost of prosecution. Such person shall also notify each such officer or employee that any such unauthorized further disclosure of Social Security information may also result in an award of civil damages against the officer or employee in an amount not less than \$1,000 with respect to each instance of unauthorized disclosure. These penalties are prescribed by IRC Sections 7213 and 7431 and set forth at 26 CFR 301.6103(n).

Additionally, it is incumbent upon the contractor to inform its officers and employees of penalties for improper disclosure implied by the Privacy Act of 1974, 5 USC 552a. Specifically, 5 USC 552a (i) (1), which is made applicable to contractors by 5 USC 552a (m) (1), provides that any officer or employee of a contractor, who by virtue of his/her employment or official position, has possession of or access to agency records which contain individually identifiable information, the disclosure of which is prohibited by the Privacy Act or regulations established there under, and who knowing that disclosure of the specific material is prohibited, willfully discloses that material in any manner to any person or agency not entitled to receive it, shall be guilty of a misdemeanor and fined not more than \$5,000.

#### **H. Contract a Public Record**

Upon signing of this contract by all parties, the terms of the contract become available to the public pursuant to Alabama law. Contractor agrees to allow public access to all documents, papers, letters, or other materials subject to the current Alabama law on disclosure. It is expressly understood that substantial evidence of Contractor's refusal to comply with this provision shall constitute a material breach of contract.

**I. Termination for Bankruptcy**

The filing of a petition for voluntary or involuntary bankruptcy of a company or corporate reorganization pursuant to the Bankruptcy Act shall, at the option of Medicaid, constitute default by Contractor effective the date of such filing. Contractor shall inform Medicaid in writing of any such action(s) immediately upon occurrence by the most expeditious means possible. Medicaid may, at its option, declare default and notify Contractor in writing that performance under the contract is terminated and proceed to seek appropriate relief from Contractor.

**J. Termination for Default**

Medicaid may, by written notice, terminate performance under the contract, in whole or in part, for failure of Contractor to perform any of the contract provisions. In the event Contractor defaults in the performance of any of Contractor's material duties and obligations, written notice shall be given to Contractor specifying default. Contractor shall have 10 calendar days, or such additional time as agreed to in writing by Medicaid, after the mailing of such notice to cure any default. In the event Contractor does not cure a default within 10 calendar days, or such additional time allowed by Medicaid, Medicaid may, at its option, notify Contractor in writing that performance under the contract is terminated and proceed to seek appropriate relief from Contractor.

**K. Termination for Unavailability of Funds**

Performance by the State of Alabama of any of its obligations under the contract is subject to and contingent upon the availability of state and federal monies lawfully applicable for such purposes. If Medicaid, in its sole discretion, deems at any time during the term of the contract that monies lawfully applicable to this agreement shall not be available for the remainder of the term, Medicaid shall promptly notify Contractor to that effect, whereupon the obligations of the parties hereto shall end as of the date of the receipt of such notice and the contract shall at such time be cancelled without penalty to Medicaid, State or Federal Government.

**L. Proration of Funds**

In the event of proration of the funds from which payment under this contract is to be made, this contract will be subject to termination.

**M. Termination for Convenience**

Medicaid may terminate performance of work under the Contract in whole or in part whenever, for any reason, Medicaid, in its sole discretion determines that such termination is in the best interest of the State. In the event that Medicaid elects to terminate the contract pursuant to this provision, it shall so notify the Contractor by certified or registered mail, return receipt requested. The termination shall be effective as of the date specified in the notice. In such event, Contractor will be entitled only to payment for all work satisfactorily completed and for reasonable, documented costs incurred in good faith for work in progress. The Contractor will not be entitled to payment for uncompleted work, or for anticipated profit, unabsorbed overhead, or any other costs.

**N. Force Majeure**

Contractor shall be excused from performance hereunder for any period Contractor is prevented from performing any services pursuant hereto in whole or in part as a result of an act of God, war, civil disturbance, epidemic, court order; such nonperformance shall not be a ground for termination for default.



#### **O. Nondiscriminatory Compliance**

Contractor shall comply with Title VII of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, Executive Order No. 11246, as amended by Executive Order No. 11375, both issued by the President of the United States, the Americans with Disabilities Act of 1990, and with all applicable federal and state laws, rules and regulations implementing the foregoing statutes with respect to nondiscrimination in employment.

#### **P. Conflict of Interest**

The parties acknowledge and agree that the Contractor must be free of conflicts of interest in accordance with all federal and state regulations while performing the duties within the contract and this amendment. The Contractor and Medicaid agree that each has no conflict of interest preventing the execution of this Contract amendment or the requirements of the original contract, and said parties will abide by applicable state and federal regulations, specifically those requirements found in the Office of Federal Procurement Policy Act. 41 U.S.C.A. 2101 through 2107.

#### **Q. Open Trade**

In compliance with Section 41-16-5 Code of Alabama (1975), the Contractor hereby certifies that it is not currently engaged in, and will not engage in, the boycott of a person or an entity based in or doing business with a jurisdiction with which this state can enjoy open trade.

#### **R. Small and Minority Business Enterprise Utilization**

In accordance with the provisions of 45 CFR Part 75.330 and OMB Circular A-102, affirmative steps shall be taken to assure that small and minority businesses are utilized when possible as sources of supplies, equipment, construction, and services.

#### **S. Worker's Compensation**

Contractor shall take out and maintain, during the life of this contract, Worker's Compensation Insurance for all of its employees under the contract or any subcontract thereof, if required by state law.

#### **T. Employment of State Staff**

Contractor shall not knowingly engage on a full-time, part-time, or other basis during the period of the contract any professional or technical personnel, who are or have been in the employment of Medicaid during the previous twelve (12) months, except retired employees or contractual consultants, without the written consent of Medicaid. Certain Medicaid employees may be subject to more stringent employment restrictions under the Alabama Code of Ethics, §36-25-1 et seq., Code of Alabama 1975.

#### **U. Immigration Compliance**

Contractor will not knowingly employ, hire for employment, or continue to employ an unauthorized alien within the State of Alabama. Contractor shall comply with the requirements of the Immigration Reform and Control Act of 1986 and the Beason- Hammon Alabama Taxpayer and Citizen Protection Act (Ala, Act 2012- 491 and any amendments thereto) and certify its compliance by executing Attachment G. Contractor will document that the Contractor is enrolled in the E-Verify Program operated by the US Department of Homeland Security as required by Section 9 of Act 2012-491. During the performance of the contract, the Contractor shall participate in the

E-Verify program and shall verify every employee that is required to be verified according to the applicable federal rules and regulations. Contractor further agrees that, should it employ or contract with any subcontractor(s) in connection with the performance of the services pursuant to this contract that the Contractor will secure from such subcontractor documentation that subcontractor is enrolled in the E-Verify program prior to performing any work on the project. The subcontractor shall verify every employee that is required to be verified according to the applicable federal rules and regulations. This subsection shall only apply to subcontractors performing work on a project subject to the provisions of this section and not to collateral persons or business entities hired by the subcontractor. Contractor shall maintain the subcontractor documentation that shall be available upon request by the Alabama Medicaid Agency.

Pursuant to Ala. Code §31-13-9(k), by signing this contract, the contracting parties affirm, for the duration of the agreement, that they will not violate federal immigration law or knowingly employ, hire for employment, or continue to employ an unauthorized alien within the state of Alabama. Furthermore, a contracting party found to be in violation of this provision shall be deemed in breach of the agreement and shall be responsible for all damages resulting therefrom.

Failure to comply with these requirements may result in termination of the agreement or subcontract.

#### **V. Share of Contract**

No official or employee of the State of Alabama shall be admitted to any share of the contract or to any benefit that may arise there from.

#### **W. Waivers**

No covenant, condition, duty, obligation, or undertaking contained in or made a part of the contract shall be waived except by written agreement of the parties.

#### **X. Warranties Against Broker's Fees**

Contractor warrants that no person or selling agent has been employed or retained to solicit or secure the contract upon an agreement or understanding for a commission percentage, brokerage, or contingency fee excepting bona fide employees. For breach of this warranty, Medicaid shall have the right to terminate the contract without liability.

#### **Y. Novation**

In the event of a change in the corporate or company ownership of Contractor, Medicaid shall retain the right to continue the contract with the new owner or terminate the contract. The new corporate or company entity must agree to the terms of the original contract and any amendments thereto. During the interim between legal recognition of the new entity and Medicaid execution of the novation agreement, a valid contract shall continue to exist between Medicaid and the original Contractor. When, to Medicaid's satisfaction, sufficient evidence has been presented of the new owner's ability to perform under the terms of the contract, Medicaid may approve the new owner and a novation agreement shall be executed.

#### **Z. Employment Basis**

It is expressly understood and agreed that Medicaid enters into this agreement with Contractor and any subcontractor as authorized under the provisions of this contract as an independent Contractor

on a purchase of service basis and not on an employer-employee basis and not subject to State Merit System law.

#### **AA. Disputes and Litigation**

Except in those cases where the proposal response exceeds the requirements of the RFP, any conflict between the response of Contractor and the RFP shall be controlled by the provisions of the RFP. Any dispute concerning a question of fact arising under the contract which is not disposed of by agreement shall be decided by the Commissioner of Medicaid.

The Contractor's sole remedy for the settlement of any and all disputes arising under the terms of this contract shall be limited to the filing of a claim with the board of Adjustment for the State of Alabama. Pending a final decision of a dispute hereunder, the Contractor must proceed diligently with the performance of the contract in accordance with the disputed decision.

In the event of any dispute between the parties, senior officials of both parties shall meet and engage in a good faith attempt to resolve the dispute. Should that effort fail, and the dispute involves the payment of money, a party's sole remedy is the filing of a claim with the Board of Adjustment of the State of Alabama.

For any and all other disputes arising under the terms of this contract which are not resolved by negotiation, the parties agree to utilize appropriate forms of non-binding alternative dispute resolution including, but not limited to, mediation. Such dispute resolution shall occur in Montgomery, Alabama, utilizing where appropriate, mediators selected from the roster of mediators maintained by the Center For Dispute Resolution of the Alabama State Bar.

Any litigation brought by Medicaid or Contractor regarding any provision of the contract shall be brought in either the Circuit Court of Montgomery County, Alabama, or the United States District Court for the Middle District of Alabama, Northern Division, according to the jurisdictions of these courts. This provision shall not be deemed an attempt to confer any jurisdiction on these courts which they do not by law have, but is a stipulation and agreement as to forum and venue only.

#### **BB. Records Retention and Storage**

Contractor shall maintain financial records, supporting documents, statistical records, and all other records pertinent to the Alabama Medicaid Program for a period of three years from the date of the final payment made by Medicaid to Contractor under the contract. However, if audit, litigation, or other legal action by or on behalf of the State or Federal Government has begun but is not completed at the end of the three- year period, or if audit findings, litigation, or other legal action have not been resolved at the end of the three year period, the records shall be retained until resolution.

#### **CC. Inspection of Records**

Contractor agrees that representatives of the Comptroller General, HHS, the General Accounting Office, the Alabama Department of Examiners of Public Accounts, and Medicaid and their authorized representatives shall have the right during business hours to inspect and copy Contractor's books and records pertaining to contract performance and costs thereof. Contractor shall cooperate fully with requests from any of the agencies listed above and shall furnish free of charge copies of all requested records. Contractor may require that a receipt be given for any original record removed from Contractor's premises.

**DD. Use of Federal Cost Principles**

For any terms of the contract which allow reimbursement for the cost of procuring goods, materials, supplies, equipment, or services, such procurement shall be made on a competitive basis (including the use of competitive bidding procedures) where practicable, and reimbursement for such cost under the contract shall be in accordance with 48 CFR, Chapter 1, Part 31. Further, if such reimbursement is to be made with funds derived wholly or partially from federal sources, such reimbursement shall be subject to Contractor's compliance with applicable federal procurement requirements, and the determination of costs shall be governed by federal cost principles.

**EE. Payment**

Contractor shall submit to Medicaid a detailed monthly invoice for compensation for the deliverable and/or work performed. Invoices should be submitted to the Project Director. Payments are dependent upon successful completion and acceptance of described work and delivery of required documentation.

**FF. Notice to Parties**

Any notice to Medicaid under the contract shall be sufficient when mailed to the Project Director. Any notice to Contractor shall be sufficient when mailed to Contractor at the address given on the return receipt from this RFP or on the contract after signing. Notice shall be given by certified mail, return receipt requested.

**GG. Disclosure Statement**

The successful Contractor shall be required to complete a financial disclosure statement with the executed contract.

**HH. Debarment**

Contractor hereby certifies that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this contract by any Federal department or agency.

**II. Not to Constitute a Debt of the State**

Under no circumstances shall any commitments by Medicaid constitute a debt of the State of Alabama as prohibited by Article XI, Section 213, Constitution of Alabama of 1901, as amended by Amendment 26. It is further agreed that if any provision of this contract shall contravene any statute or Constitutional provision or amendment, whether now in effect or which may, during the course of this Contract, be enacted, then that conflicting provision in the contract shall be deemed null and void. The Contractor's sole remedy for the settlement of any and all disputes arising under the terms of this agreement shall be limited to the filing of a claim against Medicaid with the Board of Adjustment for the State of Alabama.

**JJ. Qualification to do Business in Alabama**

Should a foreign corporation (a business corporation incorporated under a law other than the law of this state) be selected to provide professional services in accordance with this RFP, it must be qualified to transact business in the State of Alabama and possess a Certificate of Authority issued by the Secretary of State at the time a professional services contract is executed. To obtain forms for a Certificate of Authority, contact the Secretary of State at (334) 242-5324 or

[www.sos.state.al.us](http://www.sos.state.al.us). The Certificate of Authority or a letter/form showing application has been made for a Certificate of Authority must be submitted with the proposal.

**KK. Choice of Law**

The construction, interpretation, and enforcement of this contract shall be governed by the substantive contract law of the State of Alabama without regard to its conflict of laws provisions. In the event any provision of this contract is unenforceable as a matter of law, the remaining provisions will remain in full force and effect.

**LL. AMMIS Interface Standards**

Contractor hereby certifies that any exchange of MMIS data with the Agency's fiscal agent will be accomplished by following the AMMIS Interface Standards Document, which will be posted on the Medicaid website.

## Appendix A: Proposal Compliance Checklist

### NOTICE TO VENDOR:

It is highly encouraged that the following checklist be used to verify completeness of Proposal content. It is not required to submit this checklist with your proposal.

Vendor Name \_\_\_\_\_

Project Director \_\_\_\_\_

Review Date \_\_\_\_\_

*Proposals for which **ALL** applicable items are marked by the Project Director are determined to be compliant for responsive proposals.*

<input checked="" type="checkbox"/> IF CORRECT	BASIC PROPOSAL REQUIREMENTS
<input type="checkbox"/>	1. Vendor's original proposal received on time at correct location.
<input type="checkbox"/>	2. Vendor submitted the specified copies of proposal and in electronic format.
<input type="checkbox"/>	3. The Proposal includes a completed and signed RFP Cover Sheet.
<input type="checkbox"/>	4. The Proposal is a complete and independent document, with no references to external documents or resources.
<input type="checkbox"/>	5. Vendor submitted signed acknowledgement of any and all addenda to RFP.
<input type="checkbox"/>	6. The Proposal includes written confirmation that the Vendor understands and shall comply with all of the provisions of the RFP.
<input type="checkbox"/>	7. The Proposal includes required client references (with all identifying information in specified format and order).
<input type="checkbox"/>	8. The Proposal includes a corporate background.
<input type="checkbox"/>	9. The Proposal includes a detailed description of the plan to design, implement, monitor, and address special situations related to the 2021-Pharmacy-01 program as outlined in the request for proposal regarding each element listed in the scope of work.
<input type="checkbox"/>	10. The response includes (if applicable) a Certificate of Authority or letter/form showing application has been made with the Secretary of State for a Certificate of Authority.
<input type="checkbox"/>	11. The response includes an E-Verify MOU with the Department of Homeland Security.
	<b>Acknowledgement and Comply Statements</b>

<input type="checkbox"/>	12. II.C Reference Tools
<input type="checkbox"/>	13. II.D Reporting
<input type="checkbox"/>	14. II.E Additional Vendor Responsibilities
<input type="checkbox"/>	15. II.F Operational Requirements

## Appendix B: Contract and Attachments

The following are the documents that must be signed **AFTER** contract award and prior to the meeting of the Legislative Contract Oversight Committee Meeting. The current copy of these documents can be found on the Q drive in the LEGAL/Contract Forms folder.

### Sample Contract

*Attachment A:* Contract Review Report for Submission to Oversight Committee

*Attachment B:* Business Associate Addendum

*Attachment C:* Immigration Status

*Attachment D:* Instructions for Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion

*Attachment E:* Letter Regarding Reporting to Ethics Commission

*Attachment F:* Disclosure Statement

*Attachment G:* Beason-Hammon Certificate of Compliance

*Attachment H:* Governor's Additional Contract Questions



Contract Number #####

CONTRACT  
BETWEEN  
THE ALABAMA MEDICAID AGENCY  
AND  
Contractor's Name

KNOW ALL MEN BY THESE PRESENTS, that the Alabama Medicaid Agency, an Agency of the State of Alabama, and Contractor's Name, Contractor, agree as follows:

Contractor shall furnish all labor, equipment, and materials and perform all of the work required under the Enter Request for Proposal or Invitation to Bid (Enter Acronym for Contract Type) Number Enter RFP , dated Enter date of RFP strictly in accordance with the requirements thereof and Contractor's response thereto.

Contractor shall be compensated for performance under this contract in accordance with the provisions of the Enter Acronym for Contract Type and the price provided on the Enter Acronym for Contract Type Cover Sheet response, in an amount not to exceed Enter Not to Exceed Amount.

Contractor and the Alabama Medicaid Agency agree that the initial term of the contract is Enter Begin Date to Enter End Date.

This contract specifically incorporates by reference the Enter Acronym for Contract Type, any attachments and amendments thereto, and Contractor's response.

In the event of any dispute between the parties, senior officials of both parties shall meet and engage in a good faith attempt to resolve the dispute. Should that effort fail and the dispute involves the payment of money, a party's sole remedy is the filing of a claim with the Board of Adjustment of the State of Alabama.

For any and all other disputes arising under the terms of this contract which are not resolved by negotiation, the parties agree to utilize appropriate forms of non-binding alternative dispute resolution including, but not limited to, mediation. Such dispute resolution shall occur in Montgomery, Alabama, utilizing where appropriate, mediators selected from the roster of mediators maintained by the Center for Dispute Resolution of the Alabama State Bar.

All services rendered by Contractor shall be as an independent contractor and not as an employee (merit or otherwise) of the State of Alabama, and Contractor shall not be entitled to or receive Merit System benefits.

By signing this contract, the contracting parties affirm, for the duration of the agreement, that they will not violate federal immigration law or knowingly employ, hire for employment, or continue to employ an unauthorized alien within the state of Alabama. Furthermore, a contracting party found to be in violation of this provision shall be deemed in breach of the agreement and shall be responsible for all damages resulting therefrom.

In compliance with Act 2016-312, the contractor hereby certifies that it is not currently engaged in, and will not engage in, the boycott of a person or an entity based in or doing business with a jurisdiction with which this state can enjoy open trade.

Failure to comply with these requirements may result in termination of the agreement or subcontract.

CONTRACTOR NAME

Alabama Medicaid Agency

This contract has been reviewed for and is approved as to content.

\_\_\_\_\_  
Contractor Signature

\_\_\_\_\_  
Stephanie McGee Azar  
Commissioner

Tax ID: \_\_\_\_\_

Date signed: \_\_\_\_\_

Date signed: \_\_\_\_\_

APPROVED:

This contract has been reviewed for legal form and complies with all applicable laws, rules, and regulations of the State of Alabama governing these matters.

\_\_\_\_\_  
Kay Ivey  
Governor, State of Alabama

\_\_\_\_\_  
Legal Counsel

**Contract Review Permanent Legislative Oversight Committee**  
Alabama State House --- Montgomery, Alabama 36130

**CONTRACT REVIEW REPORT**

(Separate review report required for each contract)

Name of State Agency: \_\_\_\_\_

Name of Contractor: \_\_\_\_\_

Contractor's Physical Street Address (No P.O. Box Accepted) \_\_\_\_\_ City \_\_\_\_\_ ST \_\_\_\_\_

Is Contractor a Sole Source? YES \_\_\_\_\_ NO X (IF YES, ATTACH LETTER)

Is Contractor organized as an Alabama Entity in Alabama? YES \_\_\_\_\_ NO \_\_\_\_\_

Is Contractor a minority and/or woman-owned business? YES \_\_\_\_\_ NO \_\_\_\_\_

If so, is Contractor certified as such by the State of Alabama? YES \_\_\_\_\_ NO \_\_\_\_\_

Check all that apply: ALDOT \_\_\_\_\_ ADECA \_\_\_\_\_ OTHER (Name) \_\_\_\_\_

Is Contractor Registered with Alabama Secretary of State to do business as a Corporation in Alabama? YES \_\_\_\_\_ NO \_\_\_\_\_

IF LLC, GIVE NAMES OF MEMBERS: \_\_\_\_\_

Is Act 2001-955 Disclosure Form Included with this Contract? YES X NO \_\_\_\_\_

Does Contractor have current member of Legislature or family member of Legislator employed? YES \_\_\_\_\_ NO \_\_\_\_\_

Was a lobbyist/consultant used to secure this Contract OR affiliated with this Contractor? YES \_\_\_\_\_ NO \_\_\_\_\_

IF YES, GIVE NAME: \_\_\_\_\_

Contract Number: C \_\_\_\_\_ (See Fiscal Policies & Procedures Manual, Page 5-8)

Contract/Amendment Total: \$ \_\_\_\_\_ (PUT AMOUNT YOU ARE ASKING FOR TODAY ONLY)

% State Funds: \_\_\_\_\_ % Federal Funds: \_\_\_\_\_ % Other Funds: \_\_\_\_\_ \*\*

\*\*Please Specify Source of Other Funds (Fees, Grants, etc.) \_\_\_\_\_

Date Contract Effective: \_\_\_\_\_ Date Contract Ends: \_\_\_\_\_

Type Contract: NEW: \_\_\_\_\_ RENEWAL: \_\_\_\_\_ AMENDMENT: \_\_\_\_\_  
If Renewal, was it originally Bid? YES \_\_\_\_\_ NO \_\_\_\_\_

If AMENDMENT, Complete A through C:

[A] ORIGINAL contract amount \$ \_\_\_\_\_

[B] Amended total prior to this amendment \$ \_\_\_\_\_

[C] Amended total after this amendment \$ \_\_\_\_\_

Was Contract Secured through Bid Process? YES \_\_\_\_\_ NO \_\_\_\_\_ Was lowest Bid accepted? YES \_\_\_\_\_ NO \_\_\_\_\_

Was Contract Secured through RFP Process? YES \_\_\_\_\_ NO \_\_\_\_\_ Date RFP was awarded: \_\_\_\_\_

Posted to Statewide RFP Database at <http://rfp.alabama.gov/Login.aspx>? YES \_\_\_\_\_ NO \_\_\_\_\_

If NO, give a brief explanation as to why not: \_\_\_\_\_

Summary of Contract Services to be Provided: \_\_\_\_\_

Why Contract Necessary AND why this service cannot be performed by merit employee: \_\_\_\_\_

*I certify that the above information is correct.*

\_\_\_\_\_  
Signature of Agency Head

\_\_\_\_\_  
Signature of Contractor

\_\_\_\_\_  
Printed Name of Agency Head

\_\_\_\_\_  
Printed Name of Contractor

Agency Contact: \_\_\_\_\_ Phone: \_\_\_\_\_

Revised 8/2/2017

**ALABAMA MEDICAID AGENCY**  
**BUSINESS ASSOCIATE AGREEMENT**

*Revised 06/2019*

This Agreement is made effective the \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_, by and between the Alabama Medicaid Agency (“Covered Entity”), an agency of the State of Alabama, and \_\_\_\_\_ (“Business Associate”) (collectively the “Parties”).

**1. BACKGROUND**

- 1.1. Business Associate agrees to perform the following services for or on behalf of Covered Entity: [Enter a description below of the service(s) to be provided with sufficient detail to ensure clarity. Delete this parenthetical guidance from the document prior to execution.]
- 
- 

- 1.2. The relationship between Covered Entity and Business Associate is such that the Parties believe Business Associate is or may be a “business associate” within the meaning of the HIPAA Rules (as defined below).
- 1.3. The Parties enter into this Business Associate Agreement with the intention of complying with the HIPAA Rules allowing a covered entity to disclose protected health information to a business associate, and allowing a business associate to create or receive protected health information on its behalf, if the covered entity obtains satisfactory assurances that the business associate will appropriately safeguard the information.

**2. DEFINITIONS**

**2.1 General Definitions**

The following terms used in this Agreement shall have the same meaning as those terms in the HIPAA Rules: Breach, Data Aggregation, Designated Record Set, Disclosure, Electronic Protected Health Information, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information, Required By Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use.

**2.2 Specific Definitions**

2.2.1 Business Associate. “Business Associate” shall generally have the same meaning as the term “business associate” at 45 C.F.R. § 160.103

2.2.2 Covered Entity. “Covered Entity” shall generally have the same meaning as the term “covered entity” at 45 C.F.R. § 160.103.

2.2.3 HIPAA Rules. “HIPAA Rules” shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 C.F.R. Part 160 and Part 164 of the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, and the implementing regulations promulgated thereunder from time to time by the U.S. Department of Health and Human Services (HHS).

**3. OBLIGATIONS OF BUSINESS ASSOCIATE**

Business Associate agrees to the following:

- 3.1 Use or disclose PHI only as permitted or required by this Agreement or as Required by Law.
- 3.2 Use appropriate safeguards to prevent use or disclosure of PHI other than as provided for by this Agreement. Further, Business Associate will implement administrative, physical and technical safeguards (including

written policies and procedures) that reasonably and appropriately protect the confidentiality, integrity and availability of electronic PHI that it creates, receives, maintains or transmits on behalf of Covered Entity as required by Subpart C of 45 C.F.R. Part 164.

- 3.3** Mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of the requirements of this Agreement.
- 3.4** Report to Covered Entity within five (5) business days any use or disclosure of PHI not provided for by this Agreement of which it becomes aware.
- 3.5** Ensure that any subcontractors that create, receive, maintain, or transmit protected health information on behalf of the Business Associate agree to the same restrictions, conditions, and requirements that apply to the Business Associate with respect to such information in accordance with 45 C.F.R. § 164.502(e)(1)(ii) and § 164.308(b)(2), if applicable.
- 3.6** Provide Covered Entity with access to PHI within thirty (30) business days of a written request from Covered Entity, in order to allow Covered Entity to meet its requirements under 45 C.F.R. § 164.524, access to PHI maintained by Business Associate in a Designated Record Set.
- 3.7** Make amendment(s) to PHI maintained by Business Associate in a Designated Record Set that Covered Entity directs or agrees to, pursuant to 45 C.F.R. § 164.526 at the written request of Covered Entity, within thirty (30) calendar days after receiving the request.
- 3.8** Make internal practices, books, and records, including policies and procedures and PHI, relating to the use and disclosure of PHI received from, or created or received by the Business Associate on behalf of, Covered Entity, available to Covered Entity or to the Secretary within five (5) business days after receipt of written notice or as designated by the Secretary for purposes of determining compliance with the HIPAA Rules.
- 3.9** Maintain and make available the information required for Covered Entity to respond to a request by an individual for an accounting of disclosures of PHI as necessary to satisfy the Covered Entity's obligations under 45 C.F.R. § 164.528.
- 3.10** Provide to the Covered Entity, within thirty (30) days of receipt of a written request from Covered Entity, the information required for Covered Entity to respond to a request by an Individual or an authorized representative for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528.
- 3.11** Maintain a comprehensive security program appropriate to the size and complexity of the Business Associate's operations and the nature and scope of its activities as defined in the Security Rule.
- 3.12** Notify the Covered Entity within five (5) business days following the discovery of a breach of unsecured PHI on the part of the Contractor or any of its sub-contractors, and
  - 3.12.1** Provide the Covered Entity the following information:
    - 3.12.1(a)** The number of recipient records involved in the breach.
    - 3.12.1(b)** A description of what happened, including the date of the breach and the date of the discovery of the breach if known.
    - 3.12.1(c)** A description of the types of unsecure protected health information that were involved in the breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other type information were involved).
    - 3.12.1(d)** Any steps the individuals should take to protect themselves from potential harm resulting from the breach.
    - 3.12.1(e)** A description of what the Business Associate is doing to investigate the breach, to mitigate harm to individuals and to protect against any further breaches.
    - 3.12.1(f)** Contact procedures for individuals to ask questions or learn additional information, which shall include the Business Associate's toll-free number, email address, Web site, or postal address.
    - 3.12.1(g)** A proposed media release developed by the Business Associate.

- 3.12.2 Work with Covered Entity to ensure the necessary notices are provided to the recipient, prominent media outlet, or to report the breach to the Secretary of Health and Human Services (HHS) as required by 45 C.F.R. Part 164, Subpart D.;
- 3.12.3 Pay the costs of the notification for breaches that occur as a result of any act or failure to act on the part of any employee, officer, or agent of the Business Associate;
- 3.12.4 Co-ordinate with the Covered Entity in determining additional specific actions that will be required of the Business Associate for mitigation of the breach.

#### **4. PERMITTED USES AND DISCLOSURES**

Except as otherwise limited in this Agreement, Business Associate may

- 4.1. Use or disclose PHI to perform functions, activities, or services for, or on behalf of, Covered Entity as agreed to, provided that such use or disclosure would not violate the Subpart E of 45 C.F.R. Part 164 if done by Covered Entity;
- 4.2. Use PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.
- 4.3. Disclose PHI for the proper management and administration of the Business Associate, provided that:
  - 4.3.1 Disclosures are Required by Law; or
  - 4.3.2 Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as Required by Law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.
- 4.4 Use PHI to provide data aggregation services to Covered Entity as permitted by 42 C.F.R. § 164.504(e)(2)(i)(B).

#### **5. REPORTING IMPROPER USE OR DISCLOSURE**

The Business Associate shall report to the Covered Entity within five (5) business days from the date the Business Associate becomes aware of:

- 5.1 Any use or disclosure of PHI not provided for by this agreement
- 5.2 Any Security Incident and/or breach of unsecured PHI

#### **6. OBLIGATIONS OF COVERED ENTITY**

The Covered Entity agrees to the following:

- 6.1 Notify the Business Associate of any limitation(s) in its notice of privacy practices in accordance with 45 C.F.R. §164.520, to the extent that such limitation may affect Business Associate's use or disclosure of PHI.
- 6.2 Notify the Business Associate of any changes in, or revocation of, permission by an Individual to use or disclose PHI, to the extent that such changes may affect the Business Associate's use or disclosure of PHI.
- 6.3 Notify the Business Associate of any restriction to the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 C.F.R. § 164.522, to the extent that such restriction may affect the Business Associate's use or disclosure of PHI.

- 6.4 Not request Business Associate to use or disclose PHI in any manner that would not be permissible under the Privacy Rule if done by Covered Entity.
- 6.5 Provide Business Associate with only that PHI which is minimally necessary for Business Associate to provide the services to which this agreement pertains.

## 7. TERM AND TERMINATION

**7.1 Term.** The Term of this Agreement shall be effective as of the effective date stated above and shall terminate when the Business Associate no longer provides agreed upon services to the Covered Entity.

**7.2 Termination for Cause.** Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity may, at its option:

- 7.2.1 Provide an opportunity for Business Associate to cure the breach or end the violation, and terminate this Agreement if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity;
- 7.2.2 Immediately terminate this Agreement; or
- 7.2.3 If neither termination nor cure is feasible, report the violation to the Secretary as provided in the Privacy Rule.

### 7.3 Effect of Termination.

7.3.1 Except as provided in paragraph (2) of this section, upon termination of this Agreement, for any reason, Business Associate shall return or destroy all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the PHI.

7.3.2 In the event that Business Associate determines that the PHI is needed for its own management and administration or to carry out legal responsibilities, and returning or destroying the PHI is not feasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction not feasible. Business Associate shall:

- 7.3.2(a) Retain only that PHI which is necessary for Business Associate to continue its proper management and administration or to carry out its legal responsibilities;
- 7.3.2(b) Return to Covered Entity or, if agreed to by Covered Entity, destroy the remaining PHI that the Business Associate still maintains in any form;
- 7.3.2(c) Continue to use appropriate safeguards and comply with Subpart C of 45 C.F.R. Part 164 with respect to electronic protected health information to prevent use or disclosure of the protected health information, other than as provided for in this Section, for as long as Business Associate retains the PHI;
- 7.3.2(d) Not use or disclose the PHI retained by Business Associate other than for the purposes for which such PHI was retained and subject to the same conditions set out at Section 4, "Permitted Uses and Disclosures" which applied prior to termination; and
- 7.3.2(e) Return to Covered Entity or, if agreed to by Covered Entity, destroy the PHI retained by Business Associate when it is no longer needed by Business Associate for its proper management and administration or to carry out its legal responsibilities.

### 7.4 Survival

The obligations of Business Associate under this Section shall survive the termination of this Agreement.

## 8. GENERAL TERMS AND CONDITIONS

- 8.1 Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the HIPAA Rules.
- 8.2 A breach of this Agreement by Business Associate shall be considered sufficient basis for Covered Entity to terminate the services of the Business Associate.

**8.3** The Parties agree to take such action as is necessary to amend this Agreement from time to time for Covered Entity to comply with the requirements of the HIPAA Rules.

IN WITNESS WHEREOF, Covered Entity and Business Associate have executed this Agreement effective on the date as stated above

**ALABAMA MEDICAID AGENCY**

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**Clay Gaddis**  
\_\_\_\_\_

Printed Name

Privacy Officer  
\_\_\_\_\_

Title

**BUSINESS ASSOCIATE**

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Title



**IMMIGRATION STATUS**

I hereby attest that all workers on this project are either citizens of the United States or are in a proper and legal immigration status that authorizes them to be employed for pay within the United States.

\_\_\_\_\_  
Signature of Contractor

\_\_\_\_\_  
Witness

**Instructions for Certification Regarding Debarment, Suspension,  
Ineligibility and Voluntary Exclusion**

(Derived from Appendix B to 45 CFR Part 76--Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion--Lower Tier Covered Transactions)

1. By signing and submitting this contract, the prospective lower tier participant is providing the certification set out therein.

2. The certification in this clause is a material representation of fact upon which reliance was placed when this contract was entered into. If it is later determined that the prospective lower tier participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the Alabama Medicaid Agency (the Agency) may pursue available remedies, including suspension and/or debarment.

3. The prospective lower tier participant shall provide immediate written notice to the Agency if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or had become erroneous by reason of changed circumstances.

4. The terms covered transaction, debarred, suspended, ineligible, lower tier covered transaction, participant, person, primary covered transaction, principal, and voluntarily excluded, have the meaning set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. You may contact the person to which this contract is submitted for assistance in obtaining a copy of those regulations.

5. The prospective lower tier participant agrees by submitting this contract that, should the contract be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency with which this transaction originated.

6. The prospective lower tier participant further agrees by submitting this contract that it will include this certification clause without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

7. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, ineligible, or voluntarily excluded from covered transactions, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the List of Parties Excluded from Federal Procurement and Nonprocurement Programs.

8. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

9. Except for transactions authorized under paragraph 5 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the Agency may pursue available remedies, including suspension and/or debarment.



KAY IVEY  
Governor

## Alabama Medicaid Agency

501 Dexter Avenue  
P.O. Box 5624  
Montgomery, Alabama 36103-5624  
www.medicaid.alabama.gov  
e-mail: almedicaid@medicaid.alabama.gov

Telecommunication for the Deaf: 1-800-253-0799

334-242-5000 1-800-362-1504



STEPHANIE MCGEE AZAR  
Commissioner

### MEMORANDUM

**SUBJECT:** Reporting to Ethics Commission by Persons Related to Agency Employees

Section 36-25-16(b) Code of Alabama (1975) provides that anyone who enters into a contract with a state agency for the sale of goods or services exceeding \$7500 shall report to the State Ethics Commission the names of any adult child, parent, spouse, brother or sister employed by the agency.

Please review your situation for applicability of this statute. The address of the Alabama Ethics Commission is:

100 North Union Street  
RSA Union Bldg.  
Montgomery, Alabama 36104

A copy of the statute is reproduced below for your information. If you have any questions, please feel free to contact the Agency Office of General Counsel, at 242-5741.

**Section 36-25-16. Reports by persons who are related to public officials or public employees and who represent persons before regulatory body or contract with state.**

- (a) When any citizen of the state or business with which he or she is associated represents for a fee any person before a regulatory body of the executive branch, he or she shall report to the commission the name of any adult child, parent, spouse, brother, or sister who is a public official or a public employee of that regulatory body of the executive branch.
- (b) When any citizen of the State or business with which the person is associated enters into a contract for the sale of goods or services to the State of Alabama or any of its agencies or any county or municipality and any of their respective agencies in amounts exceeding seven thousand five hundred dollars (\$7500) he or she shall report to the commission the names of any adult child, parent, spouse, brother, or sister who is a public official or public employee of the agency or department with whom the contract is made.
- (c) This section shall not apply to any contract for the sale of goods or services awarded through a process of public notice and competitive bidding.
- (d) Each regulatory body of the executive branch, or any agency of the State of Alabama shall be responsible for notifying citizens affected by this chapter of the requirements of this section. (Acts 1973, No. 1056, p. 1699, §15; Acts 1975, No. 130, §1; Acts 1995, No. 95-194, p. 269, §1.)



# State of Alabama Disclosure Statement

Required by Article 3B of Title 41, Code of Alabama 1975

ENTITY COMPLETING FORM

ADDRESS

CITY, STATE, ZIP  
NUMBER

TELEPHONE

STATE AGENCY/DEPARTMENT THAT WILL RECEIVE GOODS, SERVICES, OR IS RESPONSIBLE FOR GRANT AWARD

Alabama Medicaid Agency

ADDRESS

501 Dexter Avenue, Post Office Box 5624

CITY, STATE, ZIP  
NUMBER

Montgomery, Alabama 36103-5624

TELEPHONE

(334) 242-5833

This form is provided with:

☐

Contract

☐

Proposal

☐

Request for Proposal

☐

Invitation to Bid

☐

Grant

Proposal

Have you or any of your partners, divisions, or any related business units previously performed work or provided goods to any State Agency/Department in the current or last fiscal year?

☐

Yes

☐

No

If yes, identify below the State Agency/Department that received the goods or services, the type(s) of goods or services previously provided, and the amount received for the provision of such goods or services.

STATE AGENCY/DEPARTMENT  
RECEIVED

TYPE OF GOODS/SERVICES

AMOUNT

Have you or any of your partners, divisions, or any related business units previously applied and received any grants from any State Agency/Department in the current or last fiscal year?

☐

Yes

☐

No

If yes, identify the State Agency/Department that awarded the grant, the date such grant was awarded, and the amount of the grant.

STATE AGENCY/DEPARTMENT

DATE GRANT AWARDED

AMOUNT OF GRANT

- List below the name(s) and address(es) of all public officials/public employees with whom you, members of your immediate family, or any of your employees have a family relationship and who may directly personally benefit

financially from the proposed transaction. Identify the State Department/Agency for which the public officials/public employees work. (Attach additional sheets if necessary.)

NAME OF PUBLIC OFFICIAL/EMPLOYEE  
DEPARTMENT/AGENCY

ADDRESS

STATE

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2. List below the name(s) and address(es) of all family members of public officials/public employees with whom you, members of your immediate family, or any of your employees have a family relationship and who may directly personally benefit financially from the proposed transaction. Identify the public officials/public employees and State Department/Agency for which the public officials/public employees work. (Attach additional sheets if necessary.)

NAME OF  
DEPARTMENT/  
FAMILY MEMBER  
WHERE EMPLOYED

ADDRESS

NAME OF PUBLIC OFFICIAL/  
PUBLIC EMPLOYEE

STATE  
AGENCY

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If you identified individuals in items one and/or two above, describe in detail below the direct financial benefit to be gained by the public officials, public employees, and/or their family members as the result of the contract, proposal, request for proposal, invitation to bid, or grant proposal. (Attach additional sheets if necessary.)

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Describe in detail below any indirect financial benefits to be gained by any public official, public employee, and/or family members of the public official or public employee as the result of the contract, proposal, request for proposal, invitation to bid, or grant proposal. (Attach additional sheets if necessary.)

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List below the name(s) and address(es) of all paid consultants and/or lobbyists utilized to obtain the contract, proposal, request for proposal, invitation to bid, or grant proposal:

NAME OF PAID CONSULTANT/LOBBYIST

ADDRESS

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***By signing below, I certify under oath and penalty of perjury that all statements on or attached to this form are true and correct to the best of my knowledge. I further understand that a civil penalty of ten percent (10%) of the***

***Amount of the transaction, not to exceed \$10,000.00, is applied for knowingly providing incorrect or misleading information.***

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Signature

Date

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Notary's Signature

Date

Date Notary Expires

*Article 3B of Title 41, Code of Alabama 1975 requires the disclosure statement to be completed and filed with all proposals, bids, contracts, or grant proposals to the State of Alabama in excess of \$5,000.*

State of \_\_\_\_\_)

County of \_\_\_\_\_)

**CERTIFICATE OF COMPLIANCE WITH THE BEASON-HAMMON ALABAMA TAXPAYER AND CITIZEN PROTECTION ACT (ACT 2011-535, as amended by Act 2012-491)**

DATE: \_\_\_\_\_

**RE Contract/Grant/Incentive (describe by number or subject):** Enter brief contract description by and between Enter Contractor Name (Contractor/Grantee) and Alabama Medicaid Agency (State Agency or Department or other Public Entity)

The undersigned hereby certifies to the State of Alabama as follows:

1. The undersigned holds the position of \_\_\_\_\_ with the Contractor/Grantee named above, and is authorized to provide representations set out in this Certificate as the official and binding act of that entity, and has knowledge of the provisions of THE BEASON-HAMMON ALABAMA TAXPAYER AND CITIZEN PROTECTION ACT (ACT 2011-535 of the Alabama Legislature, as amended by Act 2012-491) which is described herein as "the Act".
2. Using the following definitions from Section 3 of the Act, select and initial either (a) or (b), below, to describe the Contractor/Grantee's business structure.

**BUSINESS ENTITY.** Any person or group of persons employing one or more persons performing or engaging in any activity, enterprise, profession, or occupation for gain, benefit, advantage, or livelihood, whether for profit or not for profit. "Business entity" shall include, but not be limited to the following:

- a. Self-employed individuals, business entities filing articles of incorporation, partnerships, limited partnerships, limited liability companies, foreign corporations, foreign limited partnerships, foreign limited liability companies authorized to transact business in this state, business trusts, and any business entity that registers with the Secretary of State.
- b. Any business entity that possesses a business license, permit, certificate, approval, registration, charter, or similar form of authorization issued by the state, any business entity that is exempt by law from obtaining such a business license, and any business entity that is operating unlawfully without a business license.

**EMPLOYER.** Any person, firm, corporation, partnership, joint stock association, agent, manager, representative, foreman, or other person having control or custody of any employment, place of employment, or of any employee, including any person or entity employing any person for hire within the State of Alabama, including a public employer. This term shall not include the occupant of a household contracting with another person to perform casual domestic labor within the household.

\_\_\_\_\_(a) The Contractor/Grantee is a business entity or employer as those terms are defined in Section 3 of the Act.

\_\_\_\_\_(b) The Contractor/Grantee is not a business entity or employer as those terms are defined in Section 3 of the Act.

3. As of the date of this Certificate, Contractor/Grantee does not knowingly employ an unauthorized alien within the State of Alabama and hereafter it will not knowingly employ, hire for employment, or continue to employ an unauthorized alien within the State of Alabama;
4. Contractor/Grantee is enrolled in E-Verify unless it is not eligible to enroll because of the rules of that program or other factors beyond its control.

Certified this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

\_\_\_\_\_  
Name of Contractor/Grantee/Recipient

By: \_\_\_\_\_

Its \_\_\_\_\_

The above Certification was signed in my presence by the person whose name appears above, on

this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

WITNESS: \_\_\_\_\_

\_\_\_\_\_  
Print Name of Witness

**GOVERNOR'S ADDITIONAL CONTRACT QUESTIONS  
FOR PERSONAL AND PROFESSIONAL SERVICES CONTRACTS**

**PART I.** Mark the statutory basis for the claimed exemption from the requirement of "competitive bidding, on sealed bids, to the lowest responsible bidder," Ala. Code § 41-16-20, and any applicable requirements relating to procurement of professional services. See Ala. Code §§ 41-16-72 to -79. Then check all boxes that apply beneath the claimed exemption(s).

- ☐ § 41-16-20
- ☐ § 41-16-21(a)
- ☐ § 41-16-21(b)
- ☐ § 41-16-21.1
- ☐ § 41-16-21.2
- ☐ § 41-16-72(1) (attorneys)
  - ☐ Litigation (Hourly)
    - ☒ DAG appointment letter attached
    - ☐ Governor's rate approval letter attached
  - ☐ Litigation (Contingency Fee)
    - ☐ DAG appointment letter attached
    - ☐ Written determination attached as required by § 41-16-72(1) f.2.
    - ☐ Fee within limits prescribed by § 41-16-72(1)f.3. or AG's written authorization for exceeding limits is attached
    - ☐ AG's standard contract addendum attached per § 41-16-72(1)f.7.
- Non-litigation - Justification letter attached for not using in-house counsel or AG
- ☐ § 41-16-72(1)(d) (experts)
- ☐ § 41-16-72(2) (physicians) – Provider selected from AMLC list
- ☐ § 41-16-72(3) (architects, engineers, etc.)
  - ☐ RFP or other notice of need for professional services was widely disseminated to the professional community in a full and open manner
  - ☐ The contract fees are within the approved fee schedule
- ☐ § 41-16-72(4) (other professional: \_\_\_\_\_)
  - ☐ Proposals were solicited from providers on list obtained from Purchasing Division
  - ☐ Fees of selected provider do not exceed lowest qualified proposal by 10% or more
  - ☐ If fees exceed lowest qualified proposal by 10%, justification letter is attached
- ☐ § 41-16-72(7) (exempted agencies)
- ☐ § 41-16-74 (GSA provider)
- ☐ § 41-16-75 (sole source provider)
  - ☐ No other goods or services can meet the needs of the agency, and no other vendor offers substantially equivalent goods or services that can accomplish the purposes of this contract
  - ☐ Detailed justification/explanation letter attached
  - ☐ Written approval from Purchasing Director or Finance Director attached
- ☐ § 41-16-78 (other exemptions/exceptions)

Questions about this form and any suggestions for revisions may be sent to the Governor's Legal Office (334) 242-7120 or [teresa.lee@governor.alabama.gov](mailto:teresa.lee@governor.alabama.gov)



**PART II.** Complete this section **ONLY** if contract was awarded by RFP or RFQ. **Check all that apply.**

- ☐ Solicitation was posted to online database as required by § 41-4-66.
- ☐ The solicitation was distributed to how many providers?
- ☐ The agency received responses/proposals from how many providers?
- ☐ Explanation of how proposals were evaluated:

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**PART III.** Complete this section **ONLY** if contract is for **IT (Information Technology) related services.**

- ☐ Contract is for professional services such as IT consulting or custom software/system design and development, not for off-the-shelf software or off-the-shelf cloud-based product.
- ☐ Written approval of OIT attached per § 41-4-285

If exemption from OIT approval is claimed, please explain basis:

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**PART IV.** Complete this section **ONLY** if contract is for **personal services** (employer-employee relationship).

- ☐ Approved by State Personnel Department or its Board in accordance with Section 5-5 of the State of Alabama Fiscal Policy and Procedures Manual

**PART V. COMPLETE THIS SECTION FOR ALL CONTRACTS.**

- ☐ Contract is limited to personal/professional services; any goods provided in conjunction with contract have been purchased by competitive bid in accordance with § 41-16-20.
- ☐ Contract does not contain a waiver of sovereign immunity.
- ☐ Contract does not require the state to indemnify.
- ☐ Contract contains all required clauses:
- |   |                             |
|---|-----------------------------|
| <input type="checkbox"/> Early termination clause on page:              | <u>RFP Pg</u>               |
| <input type="checkbox"/> Alternative Dispute Resolution clause on page: | <u>RFP Pg</u>               |
| <input type="checkbox"/> Merit System Exclusion clause on page:         | <u>                    </u> |
| <input type="checkbox"/> Beason-Hammon (immigration) clause on page:    | <u>Contract Amendment</u>   |
| <input type="checkbox"/> No-boycott (i.e. free trade) clause on page:   | <u>Contract Pg 1</u>        |
- ☐ Disclosure statement required by § 41-16-82 is attached (or contract is for \$5,000 or less).

**I certify that all the information provided on this form is true, correct, and complete to the best of my knowledge.**

\_\_\_\_\_  
**Agency/Department Head**

## Appendix C: Pricing

	Months	Monthly Firm and Fixed Rate	Annual Cost (Months X Monthly Firm and Fixed Rate)
Year 1	12		
Year 2	12		
Year 3	12		
Year 4	12		
Year 5	12		
<b>TOTAL 5 Year Firm and Fixed Price</b>			

The Contractor must utilize this Pricing Form to provide their Total 5 Year Firm and Fixed Price by year.

## Appendix D: Additional Attachments

### **Alabama Medicaid Agency Provider Agreement CY2021 Hemophilia Management Standards of Care**

In order to be paid for providing blood clotting factor to Alabama Medicaid recipients, the provider, \_\_\_\_\_ [NPI= \_\_\_\_\_], hereby agrees to provide, at the minimum, the following clinically appropriate items and services to their patients with hemophilia and blood clotting factor-related diseases:

- (1) Home or office delivery of blood clotting factor and supplies. All shipments/delivery of clotting factor, including overnight deliveries, must use appropriate cold chain management and packaging practices to ensure proper temperature, drug stability, integrity, and efficacy are maintained during shipment.
- (2) Educational materials and programs.
  - (a) The provider shall develop a training library at each enrolled provider location with materials for patient use, to include but not limited to, audio, video, electronic, and written materials.
  - (b) The provider shall offer educational materials to patient or family/caregiver at minimum at initiation of participation with the provider, yearly during the in-home assessment, and upon the request of Medicaid, the prescribing physician, or patient or family/caregiver.
  - (c) Topics of education shall include, but not be limited to, specific patient and family/caregiver education aimed at preventing injury that would result in a bleed, self-administration and reconstitution of blood clotting products.
- (3) Medically necessary ancillary supplies required to perform the actual IV administration of clotting factor. Supplies may be billed to Medicaid through the Durable Medical Equipment (DME) program. In addition, sharps containers and any other necessary biohazardous waste containers shall be provided, as well as pickup and disposal of waste containers according to national, state and local biohazardous waste ordinances.
- (4) Emergency telephone support 24 hours a day, 7 days a week to ensure patients are directed appropriately for care in emergent situations.
- (5) For the purposes of this Rule and the Alabama Medicaid Agency hemophilia management standards of care, “clinical staff trained in hemophilia and related blood clotting factor related diseases” is defined as follows:
  - (a) Pharmacists are required to obtain a minimum of 2 Continuing Education (CE) credit hours per year that are specific to hemophilia or related blood clotting factor-related diseases.
  - (b) Nurses and social workers are required to obtain a minimum of 4 Continuing Education (CEU) hours per year that are specific to hemophilia or related blood clotting factor-related diseases.

Continuing education must be specific to hemophilia or related blood clotting factor-related diseases and recognized by a state or national hemophilia or bleeding disorder education/support group (for example: Hemophilia Federation of America or the National Hemophilia Association).

- (6) Emergency delivery of blood clotting factor within 24 (with a target of less than 12) hours of the receipt of a prescription for a covered person’s emergent situation, or notification of the patient with an existing

valid prescription. Emphasis should be placed during patient education of the importance of keeping an adequate supply on hand and self-administration for emergent situations.

- (7) A pharmacist, nurse, and/or a case representative assigned to each patient. A case representative shall maintain, at a minimum, monthly telephone contact with the patient or family/caregiver to include, but not limited to:
- Inquiry regarding patient's current state of well-being
  - Assessment of patient/family compliance/adherence, and persistence with the medical treatment plan
  - Incidence of adverse events
  - Incidences of supply or equipment malfunctions
  - Home inventory check of factor and supplies
  - Confirmation of next delivery date

Case representatives may include administrative support staff but must coordinate with clinical staff (as described in (5) above) in the event a clinical issue should arise.

- (8) Compliance programs.
- (a) The provider must assess patient adherence on monthly telephone contact (see (7) above) and on all in-home visits by a pharmacist, nurse, or case manager.
  - (b) The provider must verify the amount of clotting factor the patient has on hand prior to each dispense. Blood clotting factor and related products are not to be sent to the patient on an auto-ship basis. The provider shall discourage "stockpiling" of product.
  - (c) The number of bleeds and infusions from the prior shipment shall be tracked to validate the need for additional product or non-compliance with the medical treatment plan.
- (9) Notification of product recalls or withdrawals.
- (a) Any stock of recalled medications/equipment/supplies shall be removed from stock and quarantined immediately.
  - (b) Any recalled items dispensed to patients shall be retrieved and quarantined; notification to patients must occur within 24 hours of the recall receipt.
  - (c) The prescribing physician shall be notified of a medication recall. A prescription for an alternative product shall be obtained, if necessary.
- (10) Visiting clinical services.
- (a) At minimum, an initial and subsequent yearly in-home assessment of the patient, family/caregiver, and environment shall be conducted by a nurse or pharmacist trained in blood clotting factor related diseases.
  - (b) Additional in-home assessments of the patient, family/caregiver, and environment deemed necessary by the physician or patient situation shall be conducted.
  - (c) Visits may be provided directly by the provider or by arrangement with a qualified local home health care agency. All hemophilia-related clinical staff must be trained in hemophilia and bleeding disorder related diseases.
- (11) A registered pharmacist trained in blood clotting factor related diseases to perform assay to prescription management. Variance in assay to prescription/target dose should not exceed +/- 10%. Providers shall strive to dispense as close to the prescribed target dose within the assay variance as possible (i.e. do not dispense 'extra' vials, even if the 'extra' vials fall within the +/-10% variance). Extra vials dispensed within the +/-10% assay variance may be subject to recoupment.

- (12) Adverse drug reaction and drug interaction monitoring and reporting.
- (a) Pharmacists shall counsel the patient or family/caregiver in accordance with the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) to encourage appropriate medication use, promote realistic therapy expectations, help recipients manage or minimize expected adverse effects and encourage compliance.
  - (b) Pharmacists shall report any issues or concerns related to the patient's medications to the physician. For significant events, utilization of the FDA 3500 MedWatch voluntary reporting form is encouraged.

- (13) Continuation of Care. The provider shall not present any bill to or collect any monies from a covered Medicaid recipient with whom the provider has agreed to the provision of services and supplies for the home treatment of bleeding episodes associated with hemophilia, except as follows:
- (a) to collect the copayments/coinsurance amounts the covered person is required to pay under the terms defined by Medicaid, or
  - (b) if the service/product has been deemed "non-covered" and the recipient has been notified in advance as outlined in the Alabama Medicaid Agency Administrative Code and Provider Billing Manual.

Upon discontinuation of services by the provider, the provider shall, at a minimum, coordinate for another designated health care provider to provide services to covered persons, prior to withdrawal of any hemophilia-related services from the home of any covered person. The provider shall continue to provide services and supplies to a covered individual until the individual obtains an alternate source of services and supplies. Every effort shall be made by the provider (including notification to the Medicaid Director of Pharmacy) to find an alternative provider to ensure that the coordination of care/transition follows the minimum standards of care as set forth in this document.

- (14) The Alabama Medicaid Agency (or its designated representative), to ensure clinically appropriate services are being given to hemophilia patients, shall monitor providers of blood clotting factor by prospective and retrospective audits, as well as administer a patient/family/caregiver satisfaction survey to include, but not limited to, measurement of:
- (a) staff availability
  - (b) staff knowledge
  - (c) timeliness of deliveries
  - (d) accuracy of supplies and equipment
  - (e) overall satisfaction

If a provider does not meet one or more of the standards for care, as outlined in this Rule, the Alabama Medicaid Agency shall provide a written notice of that determination, with an explanation therefore, to the provider. The provider will not be reimbursed for blood clotting factor or hemophilia related services until the provider meets the standards as approved by the Agency.

My signature below certifies that I, the provider, have:

- been provided and reviewed education via the hemophilia educational videos and information on Alabama Medicaid's website:  
[http://medicaid.alabama.gov/content/4.0\\_Programs/4.3\\_Pharmacy-DME/4.3.4\\_Hemophilia.aspx](http://medicaid.alabama.gov/content/4.0_Programs/4.3_Pharmacy-DME/4.3.4_Hemophilia.aspx)
- I also understand that any violation of these standards may result in recoupment of funds paid by Alabama Medicaid.

Please review, sign and return by **12/11/2020**. Failure to return by the requested date may result in holding provider's payment and/or terminating of the provider's contract.

**PRINT LEGIBLY**

Done this \_\_\_\_\_ day of \_\_\_\_\_  
(Month) (Year).

\_\_\_\_\_ (representative of pharmacy provider) I hereby  
certify that I have authority to bind

\_\_\_\_\_ (pharmacy provider) to this agreement.

Title of above representative: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

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Phone: \_\_\_\_\_

Email: \_\_\_\_\_

National Provider Identifier (NPI): \_\_\_\_\_

Notary Public: \_\_\_\_\_

Commission Expires: \_\_\_\_\_

## **ALABAMA MEDICAID AGENCY**

### *Pharmacy and Therapeutics Committee*

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TOPIC: Operating Procedures

DATE: October 2004

P&T Policy #3

*Updated: March 2016*

*July 2018*

*July 2020*

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As defined by Alabama Code §22-6-122, the Medicaid Pharmacy and Therapeutics (P&T) Committee shall review and may recommend drugs or classes of drugs (drug class as defined by the American Hospital Formulary Service or AHFS classification system) to the Alabama Medicaid Agency for inclusion in the Medicaid Preferred Drug Program. Drugs will be reviewed according to the AHFS classification. Each therapeutic class review will contain agents that share the same first six digits of the AHFS product code and are active on the Alabama Medicaid drug file. Combination products that share similar Food and Drug Administration (FDA) approved indications as other drugs within that AHFS class may be reviewed with the single entity agents from within that same AHFS class.

The P&T Committee must develop its preferred drug list recommendations by considering the clinical efficacy and safety of a product. Generics and over the counter (OTC) drugs covered by Medicaid may be considered preferred drugs without appearing on the preferred drug list. The P&T Committee will consider recommending preferred status for brand products only. However, the P&T Committee has the ability to recommend generic products be removed from preferred status.

For the purposes of P&T reviews and manufacturer reconsiderations, the recommendations of the Medicaid P&T Committee must be based on sound clinical evidence found in labeling, drug compendia and published peer reviewed clinical literature pertaining to the use of the drug. Poster board presentation, abstracts or data on file cannot be included for the review of the class or drug if no full study has been conducted and published in peer reviewed literature. Also while agents within this therapeutic class may have demonstrated positive activity via in vitro trials, the clinical significance of this activity remains unknown until fully demonstrated in well-controlled, peer-reviewed in vivo clinical trials. As such, class/product reviews and the recommendations provided are based exclusively upon the results of such clinical trials. Therefore, in vitro studies will not be included for the review of the class or drug.

#### **Public Notice**

Medicaid will provide notice to the public of Pharmacy and Therapeutics (P&T) Committee meetings and agenda items not less than (30) calendar days in advance of scheduled meetings. The notice will be provided via the Medicaid website.

Medicaid will send written notification not less than (30) calendar days prior to a meeting of the P&T Committee to pharmaceutical manufacturers whose brand name drug(s) may be considered for preferred status at said meeting. This notice will be provided via email and the Medicaid website. If an issue arises during a clinical review conducted by the P&T Committee that requires

follow-up consideration at the next P&T Committee meeting, a minimum of thirty (30) days notice will be given to affected manufacturers.

Medicaid will maintain a database of industry representatives for the purpose of correspondence and notice regarding the Preferred Drug Program. It is the responsibility of the manufacturer to provide accurate contact information to the Medicaid Pharmacy Director delegated representative and to provide update information as needed. Contact information is to be provided on the Pharmaceutical Manufacturer Contact Information Form located on the Medicaid website. It is also available from the Medicaid Pharmacy Program Office at (334) 242-5050. In the event no contact information is provided to Medicaid, the Legal Contact on file with the Medicaid Drug Rebate Program will be utilized for notices.

### **Request For Product Review**

Manufacturers may request a product review for a new pharmaceutical product falling within the scope of the Preferred Drug Program. A new product is defined as any new drug entity (approved under a New Drug Application and identified as a Reference Listed Drug in the FDA Online Orange Book), including but not limited to combination products and line extensions, that has not been previously commercially available.

If a product that is currently commercially available has a new dosage form, it is not considered a new product and would not be eligible for a new product review before the P&T Committee. These products would be included in the review of the entire AHFS class unless there is a new indication for the product.

- a. Requests for product reviews by pharmaceutical manufacturers must be submitted in writing and directed to the Medicaid Pharmacy Director or delegated representative.
- b. Requests by pharmaceutical manufacturers for product reviews of drugs will be considered in the order in which they are received unless Medicaid identifies a need to place a higher priority on a particular class/drug.
- c. A product or a product with a new indication must have been on the market for a minimum of 180 days prior to a request for product review by a pharmaceutical manufacturer.

Manufacturers may submit written evidence supporting inclusion of a product on the Preferred Drug List to the Medicaid Pharmacy Clinical Support Personnel or delegated representative and should be clearly labeled as a request for product review. This information may be submitted to Medicaid or its delegated representative at any time after the 180 day requirement. However, the scheduling of the product's review will be at Medicaid's discretion.

### **Manufacturer Written Comments**

Manufacturers have the opportunity to present comments to the Medicaid P&T Committee as required by Act No. 2003-297 through written comments directed to the Medicaid Pharmacy Director or delegated representative.

- a. Comment period is for a period of 21 calendar days prior to the Pharmacy and Therapeutics Committee meeting. It is the responsibility of the manufacturer to verify receipt by Medicaid or its designee. If the deadline falls on a business day, the summary must be



received by 5:00 p.m. Central Time (CT). If the deadline falls on a weekend or holiday, comments must be received by noon CT of the next business day.

- b. Manufacturer comments will be restricted to products that are being reviewed for preferred status.
- c. All manufacturer comments received by the deadline must be approved to be included in the review packet provided to the P&T Committee members. Manufacturer comments **must** meet the following criteria:
  - 1. be limited to sound clinical evidence only,
  - 2. be limited to evidence-based clinical information and to Food and Drug Administration (FDA)-approved indications covered under the Alabama Medicaid Pharmacy benefit,
  - 3. exclude any reference to cost,
  - 4. exclude anecdotal content , and
  - 5. exclude general drug or disease specific economic information.

***Any comments found to contain non-compliant information regarding the above criteria will be rejected in their entirety.***

- d. Manufacturer written comments should be clearly labeled as “written comments” and should indicate the product and drug class the comments represent. Manufacturer comment submissions should be limited to one drug product per packet. Manufacturers wanting to provide written comments on more than one drug product must submit a separate packet for each product.
- e. Manufacturer comment submissions are limited to 100 pages.
- f. Manufacturer written comment submissions are limited to email, PDF format only not hard copy or CD Rom, etc.
- g. Manufacturers will receive formal written communication from the Medicaid Pharmacy Director or delegated representative alerting them if the written comments have been accepted or rejected.
- h. All manufacturer comment submissions must meet all criteria, received by the stated deadline and be approved Medicaid or its designee to be included in the review packet. Failure to abide by all of these requirements upon submission will result in a rejection of the clinical comments in their entirety. Manufacturers are also encouraged to submit information as soon as possible. Waiting until just days prior to the deadline for submission of these materials may not allow time for corrections and resubmission prior to the deadline. **No submissions or resubmissions will be accepted after the designated deadline.**

### **Manufacturer Oral Presentations**

Manufacturers have the opportunity to make oral presentations to the Medicaid P&T Committee as required by Act No. 2003-297 through a brief oral summary of their product. Oral Presentations will be restricted to products that are being reviewed for preferred status.

## 1. Oral Presentation Summary

- a. Written submission of a one page summary (1 copy, single-sided) of the material to be presented at the P&T meeting must be received by the Medicaid Pharmacy Director or delegated representative a minimum of 21 calendar days prior to the scheduled P&T meeting. It is the responsibility of the manufacturer to verify receipt by Medicaid or its designee. If the deadline falls on a business day, the summary must be received by 5:00 p.m. CT. If the deadline falls on a weekend or holiday, the summary must be received by noon CT of the next business day.
- b. Oral presentation summaries will be restricted to products that are being reviewed for preferred status.
- c. The summary must include all major points to be made during the presentation and a complete summary of the information to be shared at the meeting. This document including any references must be included on a single side of the document. The summary may not include references, package inserts or any other information on the reverse side of the document. Copies, provided by Medicaid, will be distributed to the P&T Committee members at the time of the meeting.
- d. The oral presentation summary should be clearly labeled as “Oral Presentation Summary”.
- e. Submissions are limited to email, PDF format only, not hard copy or CD-Rom, etc.
- f. Manufacturer oral comments **must** meet the following criteria:
  1. be limited to sound clinical evidence only,
  2. be limited to evidence-based clinical information and to Food and Drug Administration (FDA)-approved indications covered under the Alabama Medicaid Pharmacy benefit,
  3. exclude any reference to cost,
  4. exclude anecdotal content,
  5. exclude general drug or disease specific economic information, and
  6. reference statistical information.

***Any comments found to contain non-compliant information regarding the above criteria will be rejected in their entirety.***
- g. The oral presentation summary should be limited to one drug product per submission. Manufacturers wanting to provide an oral presentation on more than one drug product must submit a separate one-page summary for each product.
- h. All statistics identified for discussion must be supported by noting the source from which the information was obtained. This information does not have to be in formal reference form.
- i. Manufacturers will receive formal written communication from the Medicaid Pharmacy Director or delegated representative alerting them if the oral presentation summary has been accepted or rejected.

- j. All oral presentation summary submissions must meet all criteria, received by the stated deadline and be approved Medicaid or its designee to be included in the review packet. Failure to abide by all of these requirements upon submission will result in a rejection of the oral presentation summaries in their entirety. Manufacturers are also encouraged to submit information as soon as possible. Waiting until just days prior to the deadline for submission of these materials may not allow time for corrections and resubmission prior to the deadline. **No submissions or resubmissions will be accepted after the designated deadline.**

## 2. Oral Presentations

- a. Oral presentations will be restricted to products that are being reviewed for preferred status.
- b. Presentations will be limited to a maximum of five (5) minutes per representative per drug product. Each drug product will be treated as a separate presentation. In the event a manufacturer has more than one drug product in a drug class, each drug product is allowed a five (5) minute presentation. The same representative may perform the separate presentations in a drug class.
- c. Presentations will be limited to one representative per product. Only one presentation per product will be permitted.
- d. Presenters must register with Medicaid at P&T meetings a minimum of ten (10) minutes prior to the scheduled start time of the meeting. A sign-in sheet will be provided at a registration table at the meeting location. Those not registered by the designated cut off time will not be allowed to make presentations. It is the sole responsibility of the manufacturer to ensure that the presenter has signed in by the designated timeframe.
- e. Representatives will be called to present in the order in which they signed in by drug class. At the initiation of the 5 minute presentation, the speaker will be required to state any financial interest in or other relationship with the manufacturer of any of the product(s) the speaker intends to discuss.
- f. The Chairman will call for presentations by drug class. The oral presentation period will immediately precede the clinical review of each drug class. Medicaid's Contractor will then present clinical reviews by class. All questions regarding specific products and/or AHFS drug classes will be answered by the clinical contractor after the clinical review of the class.
- g. Presentations must be limited to verbal comments. No visual aids other than the designated handouts are permitted.
- h. Presentations must be limited to comments regarding the branded products within the class being considered for preferred status at the current meeting.
- i. Presentations are to be limited to clinical issues approved in the single sided oral presentation summary. Presenters will be stopped if information other than the approved

oral presentation summary is presented. Oral presentations should follow the one page summary that was submitted to and approved by Medicaid.

- j. Oral Presentations will be allowed subject to time constraints at the discretion of the Chairman or the Medicaid Commissioner so that the P&T Committee's ability to complete the planned agenda is not impeded.

### **Meeting Attendance**

Attendees of meetings are to limit distractions to a strict minimum. Cellular telephones, pagers and other media devices must be turned off or to silent mode before entering the meeting room.

All attendees of the P&T Committee meetings are to sign-in at the registration table.

### **Public Information**

P&T Committee review packet will be posted to the Medicaid website by close of business the day prior to the P&T meeting. The review packet will not be available for distribution or purchase at the sign-in table.

Medicaid shall post the PDL decisions to the Medicaid website on the 10<sup>th</sup> business day following the date of the P&T Committee meeting.

Medicaid shall post the meeting minutes to the Medicaid website within 45 days following the date of the P&T Committee meeting.

Notice of prior authorization will be posted to the Medicaid website a minimum of two weeks prior to the implementation of the PA. In addition, the prior authorization request form and criteria updates (or their location on the website) will also be posted with this notice.

### **Reconsideration Process**

Manufacturers may request a reconsideration of a clinical recommendation of the P&T Committee if there is new clinical evidence-based, peer reviewed information to consider that was not presented during the P&T review. A written request must be submitted to the Medicaid Pharmacy Director or designated representative and must be received within thirty (30) calendar days of the posting of the PDL decisions to the Medicaid website.

A request must meet the following criteria:

1. be submitted via email, PDF format only, not hard copy or CD-Rom, etc.,
2. be clearly labeled as a Clinical Reconsideration Request,
3. include new clinical evidence-based information to consider that was not presented during the P&T review, and
4. include manufacturer contact information.

Medicaid will respond in writing to all appeals within ninety (90) calendar days of receipt. Responses will be sent via US Mail.

### **General**

Medicaid staff reserves the right to delete agenda items if deemed necessary due to time constraints of the meeting.

General information, requests or questions regarding P&T or PDL should be directed to Alabama Medicaid P&T designated contact person unless otherwise stated.

This policy is posted on Alabama Medicaid's website as the Pharmacy and Therapeutic Committee's Operating Procedures.

**P&T and PDL CONTACT INFORMATION:**

Alabama Medicaid Agency  
Kelli Littlejohn Newman, Pharm.D., Director  
Clinical Services and Support  
501 Dexter Avenue  
P. O. Box 5624  
Montgomery, AL 36103-5624  
Telephone: (334) 242-5050  
Fax: (334) 353-7014  
Email: [Kelli.Littlejohn@medicaid.alabama.gov](mailto:Kelli.Littlejohn@medicaid.alabama.gov)  
Medicaid website: [www.medicaid.alabama.gov](http://www.medicaid.alabama.gov)

## **POLICY AND PROCEDURES FOR MEETING WITH PHARMACEUTICAL MANUFACTURERS**

In the spirit of fairness, consistency and integrity, the following policy and procedures will apply to all meetings between Medicaid and representatives of the pharmaceutical industry (hereafter referred to as PI reps):

1. All meetings between Medicaid and PI reps must be scheduled in advance. PI reps making cold calls to the Medicaid office will not be given a forum.
2. Priorities on meeting dates between Medicaid and PI reps will be determined by the agenda and priorities of the Alabama Medicaid Agency.
3. All meetings must be requested in writing. All requests should include the purpose for the meeting as well as contact information for the requestor. Requests may be sent via email, FAX or US Mail.
4. Upon receipt of a request for a meeting, Medicaid will make a determination of appropriate action. If Medicaid determines that the request can be handled without a meeting, the PI rep will be notified. If Medicaid determines that a meeting is required, the PI rep will be contacted for scheduling.
5. Medicaid will not grant meetings to PI reps for the purpose of introductions. Scheduled DUR Board and P&T Committee meetings are open to the public and are the ideal time to meet Medicaid staff.
6. Medicaid will not grant meetings to PI reps for the purpose of product presentations. If there is a valid concern regarding Medicaid policy governing a product, information detailing the concern/issue should be submitted in writing to the Medicaid Pharmacy Program Manager.
7. Only submitted and approved agenda items may be discussed during a meeting between Medicaid and PI reps. If further unrelated issues are identified during a meeting, a separate meeting will need to be requested.
8. The pharmaceutical industry is expected to limit to two (2), the number of PI reps to meet with Medicaid unless Medicaid has granted approval in advance.
9. The breakfast, lunch and dinner period is excluded as a meeting time and forum.
10. This policy applies to all meetings involving the Medicaid Pharmacy Program staff and Medicaid clinical staff to include meetings pertaining to Pharmacy Program issues, product discussions, disease management opportunities and Preferred Drug Program negotiations.
11. Requests for meetings should be directed as follows:

**Kelli Littlejohn Newman, Pharm D., Pharmacy Services Director**

Email: [Kelli.Littlejohn@medicaid.alabama.gov](mailto:Kelli.Littlejohn@medicaid.alabama.gov) or FAX: (334) 353-5623

Heather Vega, Drug Rebate Unit

Email: [Heather.Vega@medicaid.alabama.gov](mailto:Heather.Vega@medicaid.alabama.gov) or FAX: (334) 353-7014

### **Contact with P&T Committee Members**

While we understand there is a level of coordination between members of the manufacturing industry and providers through the normal course of business, Alabama Medicaid ask manufacturers to respect P&T Committee members' commitment to the State of Alabama by following the procedures available through the P&T policy. Also, as outlined in the P&T Committee Statement of Integrity, Committee members agree not to have ex parte contacts or discussions with manufacturers or representatives whose drugs are presented for review. This is specifically regarding drugs to be reviewed in an upcoming Medicaid P&T meeting.

## **Alabama Medicaid Administrative Code**

(The Administrative Code for the Alabama Medicaid Pharmacy Chapter can be located in its entirety at the following link:

[https://medicaid.alabama.gov/documents/9.0\\_Resources/9.2\\_Administrative\\_Code/9.2\\_Adm\\_Code\\_Chap\\_16\\_Pharmaceutical\\_Services\\_12-14-20.pdf](https://medicaid.alabama.gov/documents/9.0_Resources/9.2_Administrative_Code/9.2_Adm_Code_Chap_16_Pharmaceutical_Services_12-14-20.pdf) )

### **Rule No. 560-X-16-.27 Preferred Drug List**

(1) The Alabama Medicaid Agency will utilize a preferred drug list for determination of drugs available for reimbursement under the Medicaid Program. Prescriptions for drugs within the scope of the Medicaid preferred drug list that are not included on the preferred drug list require prior authorization before being reimbursed. Notwithstanding the preceding sentence, Medicaid may, to the extent permitted under 42 U.S.C. § 1396r-8(d), enter into an agreement with a manufacturer to designate a drug that is subject to prior authorization as a preferred drug. For reimbursement under the Medicaid Program, use of the Preferred Drug list is mandatory. Medicaid shall strive to ensure any restriction on pharmaceutical use does not increase overall health care costs to Medicaid.

(2) Over the counter drugs covered by Medicaid will be considered preferred drugs for purposes of this rule. Over the counter drugs will not appear on the preferred drug list.

(3) The Alabama Medicaid Agency will utilize the Pharmacy and Therapeutics Committee to review and recommend drugs for the Preferred Drug List. The Committee will consist of three clinical pharmacists licensed to practice in the state of Alabama and at least five physicians licensed to practice medicine in the state of Alabama. Physician members will be appointed by the Medicaid Commissioner from a list of at least two nominees for each position submitted by Medical Association of the State of Alabama. Clinical pharmacist members will be nominated by the Alabama Pharmacy Association and appointed by the Medicaid Commissioner; pursuant to state law governing professional services. Members will serve staggered two year terms and may be reappointed to the Pharmacy and Therapeutics Committee for additional terms.

(4) Drugs will be considered for the preferred drug list based on the following:

- (a) clinical efficacy
- (b) side effect profiles
- (c) appropriate usage
- (d) cost

(5) Meetings of the Pharmacy and Therapeutics Committee shall meet the requirements of the State open meetings law, and documents relating to a recommendation by the Committee shall be available under the State's public records law.



(6) Pharmaceutical manufacturers may request a product review by the Medicaid Pharmacy and Therapeutics Committee of any new pharmaceutical product falling within the scope of the Medicaid preferred drug list. The request must be in writing and directed to the Pharmacy Program Director or authorized representative. Reviews will be placed on the agenda for review in the order in which they are received.

(7) Medicaid will maintain a database of industry representatives for correspondence and notice regarding the Preferred Drug Program. Manufacturers are responsible for providing accurate contact information to Medicaid. Medicaid will update the information bi-annually. If no contact information is provided, Medicaid will utilize contact information on file with the Medicaid Drug Rebate Program.

(8) Medicaid will send written notice not less than thirty (30) calendar days prior to a meeting of the Pharmacy and Therapeutics Committee to manufacturers whose brand name drug(s) will be considered for preferred status at the meeting.

(9) A product or a product with a new indication must have been on the market for a minimum of six (6) months before a review can be requested by a pharmaceutical manufacturer. Requests must be in writing and clearly labeled as a request for product review. Evidence supporting inclusion of the product may be submitted in writing and clearly labeled as part of the request for product review.

(10) Pharmaceutical manufacturers may submit evidence supportive of inclusion of a product on the Medicaid Preferred Drug List to be reviewed by the Pharmacy and Therapeutics Committee. Written comments must meet the following requirements:

- (a) Must be received by Medicaid at least twenty-one (21) calendar days prior to the Pharmacy and Therapeutics Committee meeting. Deadlines falling on weekends or holidays must be received by noon CST of the next business day.

- (b) Must be clinically based.

- (c) Must not contain cost information. Submissions with cost information will be rejected in its entirety.

- (d) Must be clearly labeled and indicate the class of products represented.

- (e) Must provide to Medicaid twenty (20) copies by the deadline.

(11) Pharmaceutical manufacturers may make oral presentations to the Pharmacy and Therapeutics Committee on products being reviewed for preferred status. Oral presentations must meet the following requirements:

- (a) Limited to five (5) minutes per drug class.

- (b) Limited to one (1) representative and one (1) presentation per product.

(c) Limited to branded products within the class being considered.

(d) No cost information can be addressed. Inclusion of cost information will terminate the presentation.

(e) Must submit a one (1) page summary of the presentation twenty-one (21) calendar days prior to the meeting. See 10(a) above.

(f) Must provide twenty (20) copies if summary is to be distributed to Committee members at meeting. Copies must be submitted to Medicaid at sign-in.

(g) Presenters must sign-in at the registration table a minimum of ten (10) minutes prior to the scheduled start time of meeting. Failure to sign-in will result in elimination of the oral presentation.

(h) No visual aids other than designated handouts are allowed.

(12) Manufacturers may request a reconsideration of a clinical recommendation of the Pharmacy and Therapeutics Committee. Written requests should be submitted to the Medicaid Pharmacy Director and received no later than thirty (30) calendar days following the posting of the final Preferred Drug List to the Medicaid website. Requests must include clinical documentation including references to justify a reconsideration. Manufacturer contact information should be included with the submission. Medicaid will respond to requests for reconsideration within ninety (90) calendar days of receipt.

**Author:** Heather Vega, Clinical Services and Support

**Statutory Authority:** State Plan Attachment 3.1-A and 4.18-B; Title XIX, Social Security Act; 42 CFR Section 447.331 & Section 401, et seq.; Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508).

**History:** New Rule Filed June 21, 2004; Effective September 17, 2004. Amended: Filed September 11, 2015; effective October 16, 2015. **Amended:** Filed October 20, 2020; Effective December 14, 2020.

**Online Links to Alabama Medicaid Pharmacy/Clinical Services  
Information Related to this RFP**

<b>Page Description</b>	<b>Information including, but not limited to:</b>	<b>Link</b>
Alabama Medicaid Home Page	All info	<a href="https://medicaid.alabama.gov/content/4.0_Programs/">https://medicaid.alabama.gov/content/4.0_Programs/</a>
Alabama Medicaid Pharmacy Home Page	All Pharmacy info	<a href="https://medicaid.alabama.gov/content/4.0_Programs/4.3_Pharmacy-DME.aspx">https://medicaid.alabama.gov/content/4.0_Programs/4.3_Pharmacy-DME.aspx</a>
Billing and Policy Information for Providers	Maximum Unit List, Administrative Code link, Provider Manual link	<a href="https://medicaid.alabama.gov/content/4.0_Programs/4.3_Pharmacy-DME/4.3.2_Billing_Policy_Info.aspx">https://medicaid.alabama.gov/content/4.0_Programs/4.3_Pharmacy-DME/4.3.2_Billing_Policy_Info.aspx</a>
Hemophilia Management	List of hemophilia providers, video of Standard of Care	<a href="https://medicaid.alabama.gov/content/4.0_Programs/4.3_Pharmacy-DME/4.3.4_Hemophilia.aspx">https://medicaid.alabama.gov/content/4.0_Programs/4.3_Pharmacy-DME/4.3.4_Hemophilia.aspx</a>
Pharmacy Forms and Criteria	All Prior Authorization Criteria, Forms, Nutritional Grids, Max Unit Listing	<a href="https://medicaid.alabama.gov/content/9.0_Resources/9.4_Forms_Library/9.4.13_Pharmacy_Forms.aspx">https://medicaid.alabama.gov/content/9.0_Resources/9.4_Forms_Library/9.4.13_Pharmacy_Forms.aspx</a>
Pharmaceutical Manufacturer Information	Policy for meeting with manufacturers, Contact with P&T Members	<a href="https://medicaid.alabama.gov/content/4.0_Programs/4.3_Pharmacy-DME/4.3.5_Mfg_Info.aspx">https://medicaid.alabama.gov/content/4.0_Programs/4.3_Pharmacy-DME/4.3.5_Mfg_Info.aspx</a>
Pharmacy and Therapeutics Committee	Committee Information, Meeting information, Historical Meeting Documents/Reviews, Proposed Class Review Schedules through 2019	<a href="https://medicaid.alabama.gov/content/4.0_Programs/4.3_Pharmacy-DME/4.3.6_PandT_Committee.aspx">https://medicaid.alabama.gov/content/4.0_Programs/4.3_Pharmacy-DME/4.3.6_PandT_Committee.aspx</a>
Preferred Drug List (PDL)	Various Drug Listings, Related Links	<a href="https://medicaid.alabama.gov/content/4.0_Programs/4.3_Pharmacy-DME/4.3.7_Prefered_Drug_List.aspx">https://medicaid.alabama.gov/content/4.0_Programs/4.3_Pharmacy-DME/4.3.7_Prefered_Drug_List.aspx</a>